Office-Supreme Court, U.S.
FILED
SEP 16 1983
ALEXANDER L. STEVAS,
CLERK

No. 82-1772

In the Supreme Court of the United States

OCTOBER TERM, 1983

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

FREEMAN H. RINGER, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE PETITIONER

REX E. LEE
Solicitor General

J. PAUL MCGRATH
Assistant Attorney General

KENNETH S. GELLER
Deputy Solicitor General

EDWIN S. KNEEDLER
Assistant to the Solicitor General

ANTHONY J. STEINMEYER
MARGARET E. CLARK
Attorneys

Department of Justice
Washington, D.C. 20530
(202) 633-2217

QUESTIONS PRESENTED

1. Whether the district court had jurisdiction under 28 U.S.C. 1331 or 1361 to consider respondents' challenge to the Secretary's denial of payment for particular services under the Medicare Program, notwithstanding the jurisdictional bar in 42 U.S.C. 405(h).

2. Whether respondents' failure to exhaust their administrative remedies barred them from seeking judicial review under 42 U.S.C. 405(g) of the administrative denial of their Medicare claims.

PARTIES TO THE PROCEEDING

The petitioner is the Secretary of Health and Human Services. The respondents are four individual Medicare beneficiaries—Freeman H. Ringer, Sanford Holmes, Norman R. Webster-Zieber, and Jean Vescio—and a physician, Benjamin Winter, who performs the medical procedure for which respondents contend the Secretary has erroneously denied coverage under the Medicare Program. These respondents sought to represent a class of Medicare beneficiaries who had undergone or desired to undergo the medical procedure, but the district court dismissed the suit for lack of jurisdiction before ruling on the class action issue. Pet. App. 11a.

TABLE OF CONTENTS

	Page
Opinions below	1
Jurisdiction	1
Statutory provisions involved	2
Statement	2
A. The statutory and administrative scheme	2
1. The Part B Program	2
2. The Part A Program	3
B. The background and proceedings in this case	6
1. Background	6
2. The proceedings in this case	9
Introduction and summary of argument	14
Argument:	
The court of appeals erred in concluding that the district court had jurisdiction to consider respondents' claims under the Medicare program	20
A. District court jurisdiction over this suit under 28 U.S.C. 1331 and 1361 is barred by the jurisdictional preclusion in 42 U.S.C. 405(h)	20
B. The district court did not have jurisdiction over this case under 42 U.S.C. 405(g) because respondents did not exhaust their administrative remedies and obtain a "final decision" by the Secretary on their benefit claims	36
Conclusion	50
Appendix	1a

TABLE OF AUTHORITIES

Cases:

American Ass'n of Councils of Medical Staffs v. *Califano*, 575 F.2d 1367	31

Cases—Continued: Page

American Healthcare Corp. v. *Schweiker*, 688 F.2d 1072 35
Association of American Medical Colleges v. *Califano*, 569 F.2d 101 ..... 23, 24, 29, 35
Attorney Registration and Disciplinary Comm'n v. *Schweiker*, No. 83-1132 (7th Cir. Aug. 11, 1983) .. 23-24, 27, 38
Califano v. *Sanders*, 430 U.S. 99 25
Califano v. *Yamasaki*, 442 U.S. 682 ..... 25, 33, 37
Cervoni v. *Secretary of HEW*, 581 F.2d 1010 35
Cleveland Board of Education v. *LaFleur*, 414 U.S. 632 24
Continental Can Co. v. *Marshall*, 603 F.2d 590 49
Daniel Freeman Memorial Hospital v. *Schweiker*, 656 F.2d 473 31
Dietsch v. *Schweiker*, 700 F.2d 865 34
Dr. John T. MacDonald Foundation, Inc. v. *Califano*, 571 F.2d 328, cert. denied, 439 U.S. 893 29
Ellis v. *Blum*, 643 F.2d 68 ..... 25, 34
Erika, Inc. v. *United States*, 634 F.2d 580, rev'd, 456 U.S. 201 ..... 2, 3, 18-19, 27, 28
FTC v. *Standard Oil of California*, 449 U.S. 232 50
Ferguson, In re, No. 126-12-3830 (HEW App. Coun. Oct. 18, 1979) ..... *passim*
Hadley Memorial Hospital, Inc. v. *Schweiker*, 689 F.2d 905 ..... 27, 31, 35, 43
Heckler v. *Campbell*, No. 81-1983 (May 16, 1983) .. 15, 17, 24, 25, 26, 48
Herzog v. *Secretary of HEW*, 686 F.2d 1154 35
Hopewell Nursing Home, Inc. v. *Schweiker*, 666 F.2d 34 ..... 27, 43
Humana of South Carolina, Inc. v. *Califano*, 590 F.2d 1070 ..... 27-28, 29, 31, 43
Independent Meat Packers Ass'n v. *Butz*, 526 F.2d 228 31-32
Lehman v. *Nakshian*, 453 U.S. 156 41
Leschniok v. *Heckler*, No. 82-5676 (9th Cir. Aug. 18, 1983) 35
Lopez v. *Heckler*, Civil No. 83-0697-WPE(T) (C.D. Cal. June 16, 1983), appeal pending, No. 83-6126 (9th Cir. filed Aug. 3, 1983), stay granted, No. A-145 (Sept. 9, 1983) 20, 37, 39

Cases—Continued Page

Mathews v. *Diaz*, 426 U.S. 67 ..... 37, 41, 42
Mathews v. *Eldridge*, 424 U.S. 319 ..... 15, 17, 18, 25, 33, 37, 46, 47
Mental Health Ass'n of Minnesota v. *Schweiker*, 554 F. Supp. 157, appeal pending, No. 83-1263-MN (8th Cir. argued June 14, 1983) 20
Morrison v. *Heckler*, No. C82-888V (W.D. Wash. May 27, 1983) 20
National Ass'n of Home Health Agencies v. *Schweiker*, 690 F.2d 932, cert. denied, No. 82-991 (Feb. 22, 1983) 29, 31, 44
North Dakota v. *United States*, No. 81-773 (Mar. 7, 1983) 33
Norton v. *Mathews*, 427 U.S. 524 33
Rhode Island Hospital v. *Califano*, 585 F.2d 1153 .... 27-28, 43
Rodway v. *Department of Agriculture*, 514 F.2d 809 31
Rush v. *Parham*, 625 F.2d 1150 6
Schweiker v. *Hansen*, 450 U.S. 785 37
Schweiker v. *McClure*, 456 U.S. 188 ..... 2, 3, 14, 28
Smith v. *Schweiker*, 709 F.2d 777 ..... 20, 36
Stanley v. *Illinois*, 405 U.S. 645 24
Starnes v. *Schweiker*, No. 82-1543 (4th Cir. Aug. 16, 1983) 19, 27, 28, 31
United States v. *Caceres*, 440 U.S. 741 32
United States v. *Welden*, 377 U.S. 95 33
United States ex rel. Girard Trust Co. v. *Helvering*, 301 U.S. 540 35
V.N.A. of Greater Tift County, Inc. v. *Heckler*, 711 F.2d 1020 27
Vlandis v. *Kline*, 412 U.S. 441 24
W.R. Grace & Co. v. *Local 759, Int'l Union of Rubber Workers*, No. 81-1314 (May 31, 1983) 48-49
Weinberger v. *Salfi*, 422 U.S. 749 ..... *passim*
White v. *Mathews*, 559 F.2d 852, cert. denied, 435 U.S. 908 34
Winters, In re (SSA Off. Hear. App. Feb. 27, 1982)) ..... *passim*

Constitution, statutes and regulations: Page

U.S. Const.:
Art. II, § 3 35
Amend. V (Due Process Clause) 10
Act of June 11, 1946, ch. 324, 60 Stat. 237 *et seq.* 29
Section 4, 60 Stat. 238 29
Administrative Procedure Act, 5 U.S.C. 551 *et seq.*:
5 U.S.C. 553 ..... 11, 29
5 U.S.C. 553(a)(2) 29
5 U.S.C. 553(b) 16
5 U.S.C. 555(b) 11
5 U.S.C. 703 ..... 15, 30
5 U.S.C. 706(2) 10
5 U.S.C. 706(2)(a) 11
Health Insurance for the Aged Act (Medicare Act), Title XVIII, 42 U.S.C. (& Supp. V) 1395 *et seq.* ... 2
42 U.S.C. 1395 11
42 U.S.C. 1395(c) *et seq.* 2
42 U.S.C. (Supp. V) 1395c 2, 37
42 U.S.C. (& Supp. V) 1395d 2
42 U.S.C. (& Supp. V) 1395d(a) 37
42 U.S.C. (& Supp. V) 1395f 3
42 U.S.C. (& Supp. V) 1395f(a) 37
42 U.S.C. (& Supp. V) 1395g 3, 5
42 U.S.C. 1395g(a) 6
42 U.S.C. (& Supp. V) 1395h 3
42 U.S.C. (& Supp. V) 1395j *et seq.* 2
42 U.S.C. (& Supp. V) 1395k 2
42 U.S.C. (& Supp. V) 1395*l* 2
42 U.S.C. (& Supp. V) 1395u 2
42 U.S.C. 1395u(b)(3)(B) 3
42 U.S.C. 1395u(b)(3)(C) 3
42 U.S.C. (& Supp. V) 1395x(s) 2
42 U.S.C. (& Supp. V) 1395x(v) 3
42 U.S.C. (Supp. V) 1395y(a)(1) 6, 7, 10
42 U.S.C. 1395ff(a) 3, 42, 3a
42 U.S.C. 1395ff(b) 15, 16, 18, 30, 34, 35, 37, 3a
42 U.S.C. 1395ff(b)(1)(C) 4, 37, 4a
42 U.S.C. 1395ff(b)(2) 4, 4a
42 U.S.C. 1395hh 4

Constitution, statutes and regulations—Continued Page

42 U.S.C. 1395ii 4, 18, 22
42 U.S.C. (& Supp. V) 1395*oo* 15, 18
42 U.S.C. 1395*oo*(a) 6
42 U.S.C. (& Supp. V) 1395*oo*(f) 43
42 U.S.C. (Supp. V) 1395*oo*(f)(1) 6, 16, 37
Social Security Act, 42 U.S.C. (& Supp. V) 401 *et seq.*:
42 U.S.C. 405 note 33
42 U.S.C. 405(a) 4, 10, 17, 24, 32, 48
42 U.S.C. (Supp. V) 405(b) 4, 37
42 U.S.C. (Supp. V) 405(g) ..... *passim*
42 U.S.C. 405(h) ..... *passim*
42 U.S.C. (1970 ed.) 405(h) 21
Pub. L. No. 87-748, Section 1(a), 76 Stat. 744 33
28 U.S.C. (Supp. V) 1331 ..... *passim*
28 U.S.C. 1346 ..... 12, 33
28 U.S.C. 1361 ..... 2, 16, 20, 33, 1a
20 C.F.R.:
Section 404.900(a)(5) 5, 17, 38
Sections 404.923-404.928 5
Section 404.948(b) 4, 43
Section 404.950(f) 49
Section 404.967 4
Section 404.981 4
Section 422.210 4
Section 422.408 9
42 C.F.R.:
Section 405.404 6
Section 405.405 6
Section 405.415 *et seq.* 6
Section 405.701(c) 4, 5, 17, 38, 43, 49
Section 405.702 3
Sections 405.710-405.716 4
Sections 405.718-405.718c 40
Sections 405.718-405.718e 5
Section 405.718c(a)(2) 40
Section 405.718d 40
Section 405.718e 40
Section 405.720 4

Constitution, statutes and regulations—Continued Page

Section 405.722 13
Section 405.724 4
Section 405.730 4
Sections 405.807-405.812 3
Sections 405.1662-405.1667 37

Miscellaneous:

Attorney General's Manual on the Administrative Procedure Act (1947) 29
Bureau of Program Operations, Health Care Financing Administration, U.S. Dep't of Health and Human Services, *B.P.O. Part A, Intermediary Workload Report* (May 1983) 15
36 Fed. Reg. 2532 (1971) 31
40 Fed. Reg. 53385 (1975) 40
45 Fed. Reg. (1980):
p. 71426 ..... 7, 9
pp. 71426-71427 9
p. 71427 9
p. 71429 8
p. 71431 7
pp. 71431-71432 7
47 Fed. Reg. (1982):
p. 26860 31
pp. 26860-26861 32
H.R. Rep. No. 1980, 79th Cong., 2d Sess. (1946) 30
H.R. Rep. No. 96-1167, 96th Cong., 2d Sess. (1980) 44
1 J. Moore, *Moore's Federal Practice* (2d ed. 1982) 35
Part A Intermediary Letter, No. 77-4 and Enclosure 2, [1976 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 28,152 (Jan. 1977) 6, 7
S. Rep. No. 752, 79th Cong., 1st Sess. (1945) 30
Social Security Administration, U.S. Dep't of Health and Human Services, *1983 Annual Report to Congress* 15
Social Security Administration, U.S. Dep't of Health and Human Services, *Office of Hearings and Appeals Handbook* (Apr. 1982) 43

In the Supreme Court of the United States

OCTOBER TERM, 1983

No. 82-1772

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

FREEMAN H. RINGER, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE PETITIONER

OPINIONS BELOW

The opinion of the court of appeals, as amended by orders dated December 30, 1982 and February 1, 1983 (Pet. App. 1a-10a), is reported at 697 F.2d 1291. A prior version of the opinion not incorporating the February 1, 1983 amendments is reported at 684 F.2d 643. The opinion of the district court (Pet. App. 11a-17a) is not reported.

JURISDICTION

The judgment of the court of appeals was entered on August 19, 1982 (Pet. App. 19a), and a petition for rehearing was denied on December 30, 1982 (Pet. App. 18a). By order dated March 22, 1983, Justice Rehnquist extended the time within which to file a petition for a writ of certiorari to and including April 29, 1983. The petition was filed on that date and was granted on June 27, 1983 (J.A. 34). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

The following statutory provisions are reproduced in an Appendix to this Brief (App., *infra*, 1a-4a): 28 U.S.C. (Supp. V) 1331; 28 U.S.C. 1361; and Sections 205(g) and (h) and 1869(a) and (b) of the Social Security Act, 42 U.S.C. (& Supp. V) 405(g) and (h) and 1395ff(a) and (b).

STATEMENT

This case concerns the limitations on the jurisdiction of a federal district court over a suit challenging a decision by the Secretary of Health and Human Services (HHS) denying payment for a particular medical procedure under the Health Insurance for the Aged Act (42 U.S.C. (& Supp. V) 1395 *et seq.*), commonly known as the Medicare Act.

A. The Statutory And Administrative Scheme

The Medicare Program is divided into two parts. Part A of the Act (42 U.S.C. (& Supp. V) 1395c *et seq.*) provides insurance for the reasonable cost of hospital and related post-hospital services. 42 U.S.C. (& Supp. V) 1395c and 1395d. Part B of the Act (42 U.S.C. (& Supp. V) 1395j *et seq.*) establishes a voluntary program of supplementary medical insurance covering, in general, 80% of the reasonable charges for physicians' services, medical supplies, and laboratory tests. 42 U.S.C. (& Supp. V) 1395k, 1395*l* and 1395x(s).

1. *The Part B Program*

This Court recently considered the claims adjudication process and the availability of judicial review under the Part B Medicare program in *Schweiker* v. *McClure*, 456 U.S. 188 (1982), and *United States* v. *Erika, Inc.*, 456 U.S. 201 (1982). The payment of benefits under Part B is administered by private insurance carriers pursuant to contracts entered into with the Secretary of Health and Human Services. 42 U.S.C. (& Supp. V) 1395u. The carrier makes payments on a claim either directly to the beneficiary or to the physician or other supplier

of services to whom the beneficiary has assigned his claim. 42 U.S.C. 1395u(b)(3)(B). The carrier must determine whether the services are covered by Part B and, if so, the reimbursable reasonable charge for the services. If the carrier finds that the services are not covered by Part B or determines that the payment due is less than the amount claimed, the beneficiary or his assignee is entitled to have the claim reconsidered by the carrier. 42 C.F.R. 405.807-405.812. If the claim again is denied and the amount remaining in controversy is $100 or more, the claimant is entitled to an oral hearing conducted by the carrier. 42 U.S.C. (& Supp. V) 1935u(b)(3)(C); see *Schweiker* v. *McClure*, *supra*, 456 U.S. at 191.

There is no provision for review by the Secretary of the carrier's final decision on a claim after the hearing. And in view of the relatively small amount of money involved in the typical Part B claim, Congress likewise foreclosed all judicial review of the carrier's determination. *United States* v. *Erika, Inc.*, *supra*, 456 U.S. at 208-211. Because this Court thus has made clear since this suit was filed that all judicial review of Part B claims is barred, the jurisdictional issues in this case now principally relate to the Part A program.

2. *The Part A Program*

The process for determining claims for hospital benefits under Part A of the Medicare Program is in many respects parallel to that under Part B. The Medicare Act directs the Secretary to determine benefit claims under Part A "in accordance with regulations prescribed by [her]" (42 U.S.C. 1395ff(a); see also 42 U.S.C. (& Supp. V) 1395f, 1395g and 1395x(v)), although she is authorized to enter into contracts with fiscal intermediaries under which the intermediaries determine whether particular services are covered by Part A and, if so, the amount of benefits that are payable. 42 U.S.C. (& Supp. V) 1395h; 42 C.F.R. 405.702. In view of the greater amount of money at stake in the typical Part A claim, however, Congress has provided for review by the Secre-

tary of the denial of a claim by an intermediary and a limited opportunity for judicial review of the Secretary's "final decision" denying such a claim. And unlike in the Part B program, Congress has provided for a bifurcated system of review of issues arising under Part A.

a. If the intermediary determines that particular services furnished by a hospital or other provider of services are not covered by Part A, the beneficiary is entitled to have that decision reconsidered by the Health Care Financing Administration (HCFA) in HHS. 42 C.F.R. 405.710-405.716. If HCFA determines that the services are not covered and the amount in controversy is $100 or more, the individual must be afforded an opportunity for an evidentiary hearing by the Secretary in the same manner as is provided in 42 U.S.C. 405(b) for old age, survivors, and disability claimants under Title II of the Act. See 42 U.S.C. 1395ff(b)(1)(C) and (2); 42 C.F.R. 405.720. The administrative law judge (ALJ) who conducts these hearings on behalf of the Secretary may decide a case on the written record if the individual waives his right to an oral hearing. 42 C.F.R. 405.701(c), incorporating 20 C.F.R. 404.948(b).

If the claim is denied by the ALJ, the beneficiary may seek review by the Appeals Council in HHS. 42 C.F.R. 405.701(c) and 405.724, incorporating 20 C.F.R. 404.967. If the Appeals Council also denies relief, the individual is entitled by 42 U.S.C. 1395ff(b)(1)(C) to judicial review of "the Secretary's final decision after such hearing" in the same manner as is provided in 42 U.S.C. 405(g) for claims arising under Title II of the Act. However, unlike under Title II, judicial review is available on a Part A Medicare claim only if the amount in controversy is $1000 or more. 42 U.S.C. 1395ff(b)(2); 42 C.F.R. 405.730; 20 C.F.R. 404.981 and 422.210.

Pursuant to her rulemaking authority in 42 U.S.C. 405(a)[1] and 1895hh, the Secretary has provided that a "final decision" subject to judicial review under 42 U.S.C. 405(g) is deemed to have been rendered only after the

[1] As made applicable to the Medicare Program by 42 U.S.C. 1395ii.

individual has "completed the steps of the administrative review process" described above—*i.e.*, an initial determination, reconsideration, an ALJ hearing, and Appeals Council review. See 42 C.F.R. 405.701(c), incorporating 20 C.F.R. 404.900(a)(5). The Secretary has fashioned only one narrow exception to this requirement, applicable to cases in which the facts and the Secretary's interpretation of the law are not in dispute and the only factor precluding an award is a statutory provision that the claimant alleges is unconstitutional. Compare *Weinberger* v. *Salfi*, 422 U.S. 749, 766-767 (1975). In such a case, the claimant and the Secretary may enter into a formal agreement that renders it unnecessary for the claimant to pursue administrative remedies beyond the reconsideration stage in order to obtain the requisite "final decision" for purposes of judicial review. See 42 C.F.R. 405.718-405.718e; 20 C.F.R. 404.923-404.928. But the Secretary has not authorized avoidance of the exhaustion requirement in any other situations, including cases such as that involved here, in which the claimant challenges the validity of an administrative instruction issued by the Secretary.

b. Different procedures have been established for administrative and judicial review of an intermediary's determination of the reasonable cost of services that it finds *are* covered by Part A of the Medicare Program. Payment for Part A services must be made directly to the hospital or other provider of the services, not to the beneficiary personally or his assignee, as under Part B. 42 U.S.C. (& Supp. V) 1395g. Nor is the provider reimbursed for Part A services on a claim-by-claim basis, as under Part B. Instead, funds are advanced to the provider at least monthly to cover the estimated cost of *all* services furnished by the provider to Medicare beneficiaries during the relevant period. A final settlement of the actual amount due for all such services then is made at the end of the accounting period, after the provider's total costs are allocated between its Medicare and non-Medicare patients in accordance with regulations prom-

ulgated by the Secretary. 42 U.S.C. 1395g(a); 42 C.F.R. 405.404, 405.405, 405.415 *et seq.* If the provider is dissatisfied with the intermediary's "final determination" of the total amount of payments due for the accounting period and the amount in controversy is $10,000 or more, the provider is entitled to an evidentiary hearing before the Provider Reimbursement Review Board (PRRB) appointed by the Secretary in HHS. 42 U.S.C. 1395*oo*(a). A provider that is dissatisfied with the "final decision" of the PRRB may obtain judicial review of that decision by filing a civil action in federal district court within 60 days. 42 U.S.C. (Supp. V) 1395*oo*(f)(1).

B. The Background And Proceedings In This Case

1. *Background*

Under 42 U.S.C. (Supp. V) 1395y(a)(1), payment may not be made under the Medicare Program for services that are "not reasonable and necessary for the diagnosis or treatment of illness or injury." The Secretary consistently has construed this provision to prohibit payment for services that are not recognized as an effective and proven treatment for a given medical condition; services that are experimental or investigational in nature are excluded from coverage. In applying this limitation, HCFA has instructed intermediaries and carriers that payment may be made if the particular service has come to be generally accepted by the professional medical community as an effective and proven treatment for the condition for which it is used. If the service is not generally accepted, however, authoritative evidence must be presented to establish it as safe and effective. See *Part A Intermediary Letter, No. 77-4 and Enclosure 2*, [1976 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 28,152 (Jan. 1977);[2] *Rush* v. *Parham*, 625 F.2d 1150, 1156 & n.11 (5th Cir. 1980).

[2] HHS stressed in *Intermediary Letter No. 77-4* that a determination that a particular procedure is excluded from coverage on this ground does not constitute a determination that the physician

Consistent with this policy, HCFA issued administrative instructions to Medicare Part A intermediaries and Part B carriers in January 1979 informing them that no payment was to be made for a surgical procedure known as bilateral carotid body resection (BCBR) when performed to relieve symptoms of pulmonary distress. See 45 Fed. Reg. 71431-71432 (1980) (reproducing the 1979 instructions). HCFA explained that BCBR had been "shown to lack general acceptance of the professional medical community" and that "controlled clinical studies establishing the safety and effectiveness of this procedure are needed" (*id.* at 71431). Accordingly, the instructions stated that BCBR operations to relieve pulmonary symptoms "must be considered investigational and cannot be considered reasonable and necessary within the meaning of [42 U.S.C. (Supp. V) 1395y(a)(1)]" (45 Fed. Reg. 71431).[3]

HCFA issued the instructions in 1979 on the basis of advice from the Public Health Service and a special BCBR Task Force of the National Heart, Lung and Blood Institute of the National Institutes of Health (Pet. App. 2a; 45 Fed. Reg. 71426). The Public Health Service had "consistently advised HCFA" that the BCBR procedure, when performed to relieve the symptoms of pulmonary conditions such as asthma and emphysema, lacked general acceptance by the professional medical community "because of questions concerning efficacy and safety" (*ibid.*). Similarly, the twelve-member Task Force was "unanimous in its view that before any procedure can

---

has provided "improper treatment." HHS explained that the doctor is free to determine the treatment to be given, but that the Medicare Program "is not free to pay automatically for whatever items and services are involved in every course of treatment." *Id.* ¶ 28,152, at 10600.

[3] HCFA explained, however, that carotid body resection had been accepted by the medical community as effective to remove a mass in the carotid body itself, irrespective of symptoms, and that another specialized procedure in the carotid area also could be regarded as reasonable and necessary in appropriate circumstances (45 Fed. Reg. 71431-71432).

be recommended as a therapeutic measure there should be a clear demonstration of efficacy and documentation that risk is acceptably small"; in the case of BCBR, the Task Force concluded, "neither criterion is met" (*id.* at 71429). The Task Force further observed that "[e]ven in the hands of experienced surgeons the procedure has a significant in-hospital mortality rate, and theoretical considerations suggest that the risk of hypoventilation may be increased, especially in patients with chronic obstructive pulmonary disease" (*ibid.*).

Because HCFA instructions to Medicare Part A intermediaries are not binding on ALJs who preside at hearings on Part A claims, a number of Medicare beneficiaries were able to receive payment under Part A for the hospital-related expenses of BCBR notwithstanding the 1979 HCFA instructions by obtaining a favorable ruling on the coverage issue from an ALJ. The Appeals Council, which likewise is not bound by HCFA's intermediary instructions, also allowed payment in a consolidated decision involving a number of BCBR claimants. See *In re Ferguson*, No. 126-12-3830 (HEW App. Coun. Oct. 18, 1979).[4] The Appeals Council stressed, however, that its decision applied only to the particular claimants before it; that it did "not intend that this conclusion be regarded as definitive as to the issues raised"; and that its decision was "not to be cited as precedent" in other cases (slip op. 23). The Appeals Council expressed its findings about BCBR in this tentative manner because it regarded the evidence concerning the efficacy of the procedure and the risk involved as "equivocal" and "inconclusive" (slip op. 18, 19). The Appeals Council also noted the absence of any extensive studies of the procedure and the "lack of any pertinent regulations," and it

---

[4] The carriers' denials of claims for reimbursement under Part B of the Medicare Program for physicians' and other services in connection with BCBR surgery could not be appealed administratively to HHS (see page 3, *supra*), and the carriers' denials of coverage pursuant to the 1979 HCFA instructions therefore were final and binding on the claimants.

urged HCFA to take action with respect to "clarifying regulations" (slip op. 18).

In response to these developments, on October 28, 1980, HCFA issued a formal administrative ruling—binding upon ALJs and the Appeals Council—that prohibited payments under Medicare for BCBR performed after that date. 45 Fed. Reg. 71426-71427 (1980); see 20 C.F.R. 422.408. HCFA explained that it has construed the statute to bar payment for services "that are not demonstrated to be safe and effective by acceptable clinical evidence" (45 Fed. Reg. 71426) and that, after reviewing the proceedings in *In re Ferguson* and consulting once more with the Public Health Service, it again was unable to find that BCBR is safe and effective (45 Fed. Reg. 71426-91427).

2. *The Proceedings In This Case*

a. This suit was filed in the United States District Court for the Central District of California on September 18, 1980, challenging the Secretary's policy with respect to payment for BCBR (E.R. 1-26).[5] An amended complaint was filed on November 7, 1980 (J.A. 9-28). The five plaintiffs named in the amended complaint—the respondents before this Court—are four individual Medicare beneficiaries and Dr. Benjamin Winter, a physician who developed what respondents termed the "Winter technique" of BCBR and performed the operation approximately 1,000 times (J.A. 11), and who is a principal proponent of BCBR surgery (see 45 Fed. Reg. 71427).

None of the four plaintiffs who are Medicare beneficiaries had received an Appeals Council decision on a claim for payment for BCBR at the time the amended complaint was filed. In fact, only three of the four Medicare beneficiaries—respondents Holmes, Webster-Zieber, and Vescio—had undergone BCBR surgery at that time. Respondents Holmes and Webster-Zieber had sought payment for their hospital and physicians' ex-

[5] "E.R." refers to the Excerpts of Record filed in the court of appeals.

penses in connection with their surgery under both Part A and Part B of the Medicare Program. Their Part A claims had been denied by the intermediary and by HCFA on reconsideration, but an ALJ had not yet held a hearing on the claims (J.A. 11; *In re Benjamin Winter, M.D., Representative for 132 Claimants* (SSA Off. Hear. App. Feb. 27, 1982), slip op. 5)). The Part B claims of these two respondents also had been denied by the responsible carrier (J.A. 11). Respondent Vescio had filed reimbursement claims for her BCBR surgery under Part A and Part B, but those claims had not been acted upon by the intermediary and carrier (J.A. 11; *In re Winter, supra*, slip op. 9). Respondent Ringer had not undergone the BCBR surgery when this suit was filed, and we have been informed by HHS that a search of its computer records does not disclose that he has ever filed a claim seeking payment for BCBR. These four respondents and Dr. Winter also sought to represent a class of Medicare beneficiaries who underwent or desire to undergo BCBR surgery for relief of chronic obstructive lung disease (J.A. 12), but the district court dismissed the suit for lack of jurisdiction before ruling on the question of class certification (Pet. App. 11a).

Respondents sought on a variety of grounds to prevent the Secretary from enforcing the 1979 instructions and the October 28, 1980 HCFA ruling barring payment for BCBR and to have the court declare that BCBR is a reasonable and necessary medical procedure (J.A. 25-27). They contended, *inter alia*, that the policy barring reimbursement for BCBR violated the requirement in 42 U.S.C. (Supp. V) 1395y(a)(1) that payment be made for "reasonable and necessary" services and was arbitrary and capricious under the Administrative Procedure Act (APA) (5 U.S.C. 706(2)), under the provision in 42 U.S.C. 405(a) for the Secretary to issue "reasonable" rules, and under the Due Process Clause of the Fifth Amendment (J.A. 16-18, 19, 23-24). Respondents also asserted that requiring claimants to pursue administrative appeals to the ALJ stage under Part A when inter-

mediaries were obliged to deny coverage on the basis of the 1979 instructions violated their right to prompt administrative action under 5 U.S.C. 555(b) and 706(2)(a) (J.A. 18-19). Finally, respondents contended that the Secretary violated the rulemaking provisions of the APA (5 U.S.C. 553) when the 1979 instructions and 1980 ruling were issued (J.A. 20-22).[6]

On February 18, 1981, the district court dismissed the complaint for lack of jurisdiction (Pet. App. 11a-17a). The district court found that "[t]he essence of [respondents'] claim * * * is a claim of entitlement to benefits for the BCBR procedure," and it held that such an action could not be brought under 42 U.S.C. 405(g) until the claimants had exhausted their administrative remedies (Pet. App. 14a). The district court explained that the exhaustion requirement is not discretionary with the court; that an appearance of futility does not render exhaustion unnecessary; and that exhaustion could not be regarded as futile in this case in any event because the Secretary's position concerning the reasonableness or efficacy of the BCBR procedure might change in the administrative hearings then being sought by respondents (*id.* at 14a-15a). The district court also held that exhaustion of administrative remedies could not be excused on the basis of respondents' argument that the Secretary should be collaterally estopped from "relitigating" the question of the coverage of BCBR under Medicare. The court explained that the Secretary had not yet ruled on the collateral estoppel argument in the pending administrative proceedings and that the application of collateral estoppel appeared doubtful because the Appeals Council

[6] Respondents also objected to the fact that Part A BCBR claims would be heard in the future by an ALJ other than the one who previously had considered the claims of Dr. Winter's patients (J.A. 22-23) and argued that the policy barring payment for BCBR constituted secretarial control over the practice of medicine in violation of 42 U.S.C. 1395 and unconstitutionally interfered with Dr. Winter's practice of medicine and his relationship with his patients (J.A. 19-20).

had stated in *In re Ferguson* that its ruling allowing payment for BCBR on behalf of the claimants in that case was not to have precedential effect (Pet. App. 14a-16a).

b. The court of appeals reversed the dismissal of the complaint and remanded for consideration of respondents' claims on the merits. The court of appeals recognized that under 42 U.S.C. 405(h) an action "to recover on a claim under the [Medicare] Act" can only be brought under 42 U.S.C. 405(g) and cannot be brought under 28 U.S.C. 1331 or 1361 (Pet. App. 3a-4a). But the court nevertheless held that the district court had jurisdiction under 28 U.S.C. 1331 and 1361 in this case. It found that a "major thrust" of respondents' complaint was that the Secretary's 1979 instructions and 1980 ruling barring reimbursement for BCBR constituted an "unlawful interference in the administrative process for determining benefits" (Pet. App. 5a, 3a). In the court's view, this is a "procedural" claim, not a substantive claim for benefits, and it concluded that to this extent the instant suit is not an action "to recover on [a] claim arising under" the Medicare Act for purposes of the jurisdictional bar in 42 U.S.C. 405(h) (Pet. App. 4a-6a).

The court of appeals acknowledged that respondents also contended that the Secretary had "reached an improper substantive result in the process of determining whether benefits should be awarded" (Pet. App. 6a) and that this contention did constitute a claim for benefits that had to be brought under 42 U.S.C. 405(g). It acknowledged as well that a district court has jurisdiction under 42 U.S.C. 405(g) only after the claimant has exhausted his administrative remedies (Pet. App. 6a). But the court of appeals found those requirements inapplicable in this case. It reasoned that the Secretary's issuance of the 1980 ruling requiring ALJs and the Appeals Council to deny claims for BCBR operations "indicated that [the Secretary] has no interest in appeals" (*id.* at 8a-9a) and that respondents' interest in having an initial benefit determination made "without the prejudice—and the neces-

sary appeal—resulting from the HCFA ruling" justified immediate judicial review (*id.* at 9a-10a). The court did hold, however, that the district court was without jurisdiction over the claims of individuals, such as respondent Ringer, who had not yet even applied for Medicare benefits for BCBR (*id.* at 9a n.4).

c. Although the court of appeals did not mention the point, the three respondents who had had BCBR surgery before the amended complaint was filed in this case—respondents Holmes, Webster-Zieber, and Vescio—in fact received a decision by an ALJ on their claims well before the court of appeals issued its opinion. See *In re Winter*, *supra*. The ALJ dismissed the claims of respondents Holmes and Webster-Zieber and 34 other beneficiaries without reaching the merits because Dr. Winter, as their representative, had not requested an ALJ hearing within 60 days of the decision on HCFA's reconsideration of their claims, as required by HHS regulations (slip op. 4-7; see 42 C.F.R. 405.722). The ALJ did reach the merits of the claims of respondent Vescio and 44 other beneficiaries who had had BCBR surgery before the October 28, 1980 effective date of the formal HCFA ruling.[7] However, after reviewing the extensive medical testimony and other evidence in the record (slip op. 16-33), the ALJ concluded that BCBR was not a "reasonable and necessary" procedure for those 45 claimants (slip op. 8-9, 35-44). The ALJ also rejected the claimants' argument that the Secretary was precluded by the doctrine of collateral estoppel from relitigating the BCBR coverage question by virtue of the Appeals Council's decision in *In re Ferguson*. The ALJ explained that the doctrine of preclusion was inapplicable because the Appeals Council had explicitly stated in *In re Ferguson* that its decision was not to be regarded as definitive on the

[7] The ALJ held that payment was barred under the 1980 HCFA ruling for BCBR surgery performed after October 28, 1980 (*In re Winter*, *supra*, slip op. 1-4, 34-35, 43).

issues raised and was not to be cited as precedent (*In re Winter, supra*, slip op. 15).

These and other BCBR cases have now been taken to the Appeals Council, but the Appeals Council has not yet rendered a decision on them.[8]

INTRODUCTION AND SUMMARY OF ARGUMENT

The decision of the court of appeals is flatly inconsistent with this Court's decision in *Weinberger* v. *Salfi*, 422 U.S. 749 (1975), which clearly delineates the statutorily prescribed limitations on the jurisdiction of federal district courts over claims arising under the Social Security Act. *Salfi* and its progeny require the courts to respect the terms of the special administrative and judicial review procedures carefully structured by Congress and the Secretary to assure fair, thorough, and efficient consideration of the millions of claims filed each year under the various titles of the Act.[9]

A. Under *Salfi*, by virtue of the preclusion of review in 42 U.S.C. 405(h), judicial actions seeking to establish an entitlement to payments under the Social Security Act or to remove a legal barrier to the recovery of such payments in subsequent administrative proceedings cannot be brought under 28 U.S.C. 1331. They may be brought only pursuant to whatever statutory review pro-

---

[8] After the court of appeals rendered its decision in this case, counsel for the claimants in the administrative proceedings (who is also counsel for respondents herein) requested the Appeals Council to stay its consideration of the administrative appeals from the ALJ's decision pending a decision by the district court on remand. The Appeals Council initially granted that request. Pet. 22 n.18. However, in response to a February 17, 1983 letter from the Administrator of HCFA (and despite a renewed request for a stay by respondents' counsel in a letter dated April 12, 1983), the Appeals Council has informed counsel by letter dated July 22, 1983 that it now intends to proceed with its consideration of the appeals.

[9] This Court has had occasion to note the enormous caseload under various Social Security programs, observing that there were 158 million claims for benefits filed under Part B of the Medicare Program in 1980 (*Schweiker* v. *McClure, supra*, 456 U.S. at 190)

visions Congress has made applicable in the Social Security Act itself, such as 42 U.S.C. 1395ff(b) and 405(g) in the case of individual Medicare Part A beneficiaries and 42 U.S.C. (& Supp. V) 1395*oo* in the case of Medicare providers. See 422 U.S. at 756-764. The effect of this statutory scheme is simply to channel *all* issues bearing on a particular claimant's entitlement to benefits—whether those issues are constitutional, statutory, regulatory, procedural, or evidentiary in nature—through the special administrative and judicial review procedures established under the Social Security Act. See also *Mathews v. Eldridge*, 424 U.S. 319, 327 (1976). The court of appeals' holding that the district court had jurisdiction under 28 U.S.C. 1331 over respondents' challenge to the denial of payment for BCBR ignores these limitations.

Although the court of appeals attempted to avoid the force of *Salfi* by characterizing respondents' claim as a "procedural" challenge to the "presumption" against payment for BCBR created by the 1979 instructions and 1980 ruling, this claim is essentially identical to that held in *Salfi* itself to be subject to the jurisdictional bar in Section 405(h). Nor can *Salfi* be distinguished on the ground that respondents seek only declaratory and injunctive relief, not an award of benefits. The plaintiffs in *Salfi* sought similar relief, but the Court held that jurisdiction under 28 U.S.C. 1331 was barred.

The enactment of the Administrative Procedure Act reinforces this construction of Section 405(h). Under 5 U.S.C. 703, the appropriate proceeding in which to ob-

---

and 2.3 million claims for disability benefits filed under Titles II and XVI of the Act in 1981 (*Heckler* v. *Campbell*, No. 81-1983 (May 16, 1983), slip op. 3 n.2). More recently, in 1982, there were 48 million claims filed under Part A of the Medicare Program (Bureau of Program Operations, Health Care Financing Administration, U.S. Dep't of Health and Human Services, *B.P.O. Part A, Intermediary Workload Report* (May 1983)) and 3.2 million claims filed under the old age and survivors insurance program established by Title II of the Act (Social Security Administration, U.S. Dep't of Health and Human Services, *1983 Annual Report To Congress* 43).

tain judicial review of agency action, including the issuance of a rule, is the special statutory review procedure relevant to the subject matter. In this case, the applicable statutory review procedure is contained in 42 U.S.C. 1395ff(b) and 405(g). The exemption in 5 U.S.C. 553(b) from APA rulemaking requirements for matters pertaining to "benefits"—by virtue of which Social Security beneficiaries do not even have a right to present their legal and factual objections to a rule to the *Secretary* outside of the context of an individual claim for benefits —also demonstrates that Congress did not intend to permit beneficiaries to raise such objections to a rule in a separate proceeding under 28 U.S.C. 1331 notwithstanding the explicit jurisdictional bar in 42 U.S.C. 405(h).

Nor can the congressional intent to channel all issues bearing on a Social Security claim through 42 U.S.C. 405(g) be evaded by bringing an action under the mandamus statute, 28 U.S.C. 1361. Mandamus relief would be inappropriate in this case in any event because respondents can obtain judicial review of their claims under the special statutory review provisions in the Social Security Act and because the Secretary manifestly does not owe a clear duty to respondents to make payments under Medicare for BCBR surgery or to rescind the BCBR instructions and ruling.

B. Even within the special framework of the Social Security Act, whenever Congress *has* authorized judicial review of a claim for benefits, it has done so only where the Secretary has rendered a "final decision" on the claim "after a hearing." 42 U.S.C. 405(g). See also 42 U.S.C. (& Supp. V) 1395ff(b) and 1395*oo*(f)(1). This assures that a court will become involved in considering benefit disputes only after they first have been reviewed administratively to the extent the Secretary deems necessary to assure a thorough and accurate assessment.

The Court stressed in *Salfi* that the "final decision" requirement in 42 U.S.C. 405(g) is a "statutorily specified jurisdictional prerequisite," not "simply a codification

of the judicially developed doctrine of exhaustion" (422 U.S. at 766). Accordingly, that requirement may not be dispensed with by a court on the basis of its own conclusion that further exhaustion of administrative remedies would be futile. *Ibid.* Indeed, the determination of when a decision is "final" for purposes of judicial review is "left to the *Secretary* to flesh out by regulation" (*ibid.*; emphasis added). Thus, not only is the Secretary authorized by 42 U.S.C. 405(a) and related provisions to adopt procedures for the administrative adjudication of Social Security claims; she is authorized by the same statutory provisions to specify such requirements for exhaustion of her administrative procedures "as [she] deems serve [her] own interests in effective and efficient administration." 422 U.S. at 766. See also *Mathews* v. *Eldridge*, *supra*, 424 U.S. at 328-330.

The Secretary has exercised this authority by specifying in governing regulations that, with one narrow exception applicable in the case of constitutional challenges to the Act that are beyond the competence of the Secretary to decide, an administrative denial of a claim is deemed "final" for purposes of judicial review only after the claimant has pursued *all* steps in the administrative process. 42 C.F.R. 405.701(c), incorporating 20 C.F.R. 404.900(a)(5). These regulations, adopted pursuant to authority expressly delegated by Congress, must be sustained unless they exceed the Secretary's statutory authority or are arbitrary and capricious. *Heckler* v. *Campbell*, No. 81-1983 (May 16, 1983), slip op. 8. The regulations clearly are not invalid on either ground, yet the court of appeals in this case chose not to enforce the exhaustion requirement they embody. This the court had no authority to do.

In view of the vast number of claims presented annually under the Social Security Act, the Secretary necessarily must fashion administrative procedures and corresponding exhaustion requirements with the generality of cases in mind. Just as the rules of civil and appellate procedure and statutory finality requirements governing

judicial proceedings in federal courts must be respected in all cases to which they apply, so too the procedural rules and finality requirements designed to govern the *administrative* review of a broad range of Social Security claims must be uniformly enforced in individual cases, whether or not the beneficiary or the court believes them to be sound as applied in the circumstances of a particular case. Any other result would sacrifice the certainty and ease of application of governing principles that are critical to the efficient administration of the Social Security programs and would overburden the federal courts with extensive and protracted litigation on threshold questions of jurisdiction and exhaustion of administrative remedies in Social Security cases.

To be sure, the Court in *Mathews* v. *Eldridge* fashioned a limited exception to the requirement of full exhaustion in the case of an asserted constitutional right to a pretermination hearing. But the issue there was entirely collateral to the merits of the disability claim, and the alleged injury could not have been remedied by a retroactive award of benefits if its consideration by a court were postponed until after full exhaustion of administrative remedies. 424 U.S. at 330-332. Neither of these factors is present here. Respondents simply challenge on the merits the denial of payment for particular services under the Medicare Program. This is a routine reimbursement issue that presents no basis whatever for excusing respondents from complying with the applicable exhaustion regulations.

C. It is clear that the jurisdictional and exhaustion holdings of *Weinberger* v. *Salfi* and its progeny are fully applicable to respondents' Part A Medicare claims, because the preclusion of review provision in 42 U.S.C. 405(h) applies to Medicare cases "to the same extent" as it applies to Title II cases (see 42 U.S.C. 1395ii) and the judicial review provisions in 42 U.S.C. (& Supp. V) 1395ff(b) and 1395*oo* likewise require a "final decision" as a jurisdictional prerequisite. And as to respondents' Part B claims, this Court held in *United States* v. *Erika*,

Inc., *supra*, 456 U.S. 201, that Congress has foreclosed *all* judicial review under Part B of the Medicare Program, whether the carrier's denial of a claim is based on the facts of a particular case or on an administrative instruction of general applicability issued by the Secretary.[10]

As it turns out, moreover, this case vividly illustrates why the court of appeals should have enforced the established jurisdictional and exhaustion requirements. While this case was under submission to the court of appeals, an ALJ in HHS ruled on the claims of the only three respondents who had received BCBR surgery, and it did so *without regard* to the instructions and HCFA ruling that respondents attack in this suit. The ALJ also considered the merits of the same collateral estoppel argument that respondents contend they should be permitted to present to a court without first pursuing their administrative remedies. It was precisely because of the possibility of such developments in administrative proceedings that the Court in *Salfi* foreclosed judicial review prior to a final decision by the Secretary.

The court of appeals' countenancing of a circumvention of the administrative process in these circumstances poses a serious threat to the Secretary's ability to administer the Medicare and other Social Security programs in the efficient manner Congress intended. If affirmed by this Court, it inevitably would accelerate the recent proliferation of litigation in the lower courts on questions of jurisdiction and exhaustion under the Social Security Act that impelled us to request the Court to revisit these issues despite the seemingly clear holdings of its prior cases. These are very real concerns, because we have been informed by HHS that there are now pending at

---

[10] In *Erika* itself, the carrier's denial of payments under Medicare was based in part on an instruction issued by the Secretary to Part B carriers. See *Erika, Inc.* v. *United States*, 634 F.2d 580, 590-591 (Ct. Cl. 1980); U.S. Br. at 14, *United States* v. *Erika, Inc.*, *supra* (No. 80-1594, 1980 Term). See also *Starnes* v. *Schweiker*, No. 82-1543 (4th Cir. Aug. 16, 1983), slip op. 10-11, discussed in note 18, *infra*.

least 25 Medicare cases and more than 55 other Social Security cases involving related jurisdictional issues, several of which are class actions that include thousands of claimants who have not exhausted their administrative remedies.[11] We therefore urge the Court to arrest the erosion of the principles established in *Weinberger* v. *Salfi* by reaffirming that the lower courts must strictly adhere to the preclusion of review and exhaustion provisions in 42 U.S.C. 405(g) and (h).

ARGUMENT

THE COURT OF APPEALS ERRED IN CONCLUDING THAT THE DISTRICT COURT HAD JURISDICTION TO CONSIDER RESPONDENTS' CLAIMS UNDER THE MEDICARE PROGRAM

A. District Court Jurisdiction Over This Suit Under 28 U.S.C. 1331 And 1361 Is Barred By The Jurisdictional Preclusion In 42 U.S.C. 405(h)

1. The court of appeals' holding that respondents could bring an action under 28 U.S.C. 1331 to challenge the validity of the 1979 instructions and 1980 HCFA ruling barring payment for BCBR is flatly inconsistent with this Court's decision in *Weinberger* v. *Salfi*. The named plaintiffs in *Salfi* filed applications for benefits under Title II of the Social Security Act as the surviving wife and stepchild of a deceased wage earner. Their applications were denied at the initial determination and reconsideration levels on the ground that they did not have the requisite relationship with the deceased wage earner for nine months prior to his death, as required by the Act. See 422 U.S. at 753-754, 764-765. The plaintiffs then brought an action in federal district court under 28 U.S.C. 1331

---

[11] See, *e.g.*, *Lopez* v. *Heckler*, Civ. No. 83-0697-WPE(T) (C.D. Cal. June 16, 1983), appeal pending, No. 83-6126 (9th Cir. filed Aug. 3, 1983), stay granted, No. A-145 (Sept. 9, 1983) (Rehnquist, Circuit Justice); *Morrison* v. *Heckler*, No. C82-888V (W.D. Wash. May 27, 1983); *Mental Health Ass'n of Minnesota* v. *Schweiker*, 554 F. Supp. 157 (D. Minn. 1982), appeal pending, No. 83-1263-MN (8th Cir. argued June 14, 1983). See also *Smith* v. *Schweiker*, 709 F.2d 777 (2d Cir. 1983).

contending that the statutory duration-of-relationship requirement was unconstitutional. 422 U.S. at 752-753. As relief, the plaintiffs sought a declaratory judgment that the relevant statutory provisions were unconstitutional, injunctive relief prohibiting the Secretary from denying benefits on the basis of those provisions, and the payment of benefits. The district court found jurisdiction under 28 U.S.C. 1331, held the statute unconstitutional, and granted the requested relief. 422 U.S. at 755-756. This Court held that jurisdiction over the suit under 28 U.S.C. 1331 was barred by the third sentence of 42 U.S.C. 405 (h), which provides: "'No action against the United States, the Secretary, or any officer or employee thereof shall be brought under [§ 1331 *et seq.*] of Title 28 to recover on any claim arising under [Title II of the Social Security Act].'" 422 U.S. at 756, quoting 42 U.S.C. (1970 ed.) 405(h) (brackets in the Court's opinion).[12]

The Court rejected the contention that the plaintiffs' action was not one to recover on a claim "arising under" the Social Security Act because it also arose under the Constitution. The Court reasoned that not only were plaintiffs seeking to recover Social Security benefits, but also it was the Social Security Act that provided both the standing and the substantive basis for the presentation of their constitutional contentions. 422 U.S. at 760-

---

[12] As it appeared in the 1970 and previous editions of the United States Code, 42 U.S.C. 405(h) provided:

> The findings and decisions of the Secretary after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Secretary shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Secretary, or any officer or employee thereof shall be brought under section 41 of Title 28 to recover on any claim arising under this subchapter.

In the 1976 edition of Title 42, which has not been enacted into positive law, the phrase "sections 1331 or 1346 of title 28" was substituted for the reference in the third sentence to "section 41 of Title 28." See page 33, *infra*.

761. Thus, the Court concluded, the jurisdictional bar in the third sentence of Section 405(h) "extends to any 'action' seeking 'to recover on any [Social Security] claim'—irrespective of whether resort to judicial processes is necessitated by discretionary decisions by the Secretary or by his nondiscretionary application of allegedly unconstitutional statutory restrictions." 422 U.S. at 762, quoting 42 U.S.C. 405(h) (brackets in the Court's opinion). The Court explained that the effect of 42 U.S.C. 405(h) in *Salfi* was simply to require that the plaintiffs' constitutional challenge be brought under the special jurisdictional grant in the Social Security Act, "and thus in conformity with the same standards which are applicable to nonconstitutional claims arising under the Act. The result is not only of unquestionable constitutionality, but it also is manifestly reasonable, since it assures the Secretary the opportunity prior to constitutional litigation to ascertain, for example, that the particular claims involved are neither invalid for other reasons nor allowable under other provisions of the Social Security Act." 422 U.S. at 762.

By virtue of 42 U.S.C. 1395ii, Section 405(h) applies to the Medicare Act "to the same extent" as it applies to Title II of the Social Security Act. The decision in *Salfi* therefore controls here. If Section 405(h) precludes jurisdiction under 28 U.S.C. 1331 even over a suit challenging a *statutory prohibition* barring the payment of benefits in a certain category of cases, as the Court held in *Salfi*, a fortiori Section 405(h) must bar federal question jurisdiction over a suit challenging the validity of an *administrative ruling* issued by the Secretary pursuant to the statute that also prohibits the payment of benefits in a certain category of cases.[13] A challenge to

[13] It is instructive in this regard that even the dissenting opinion in *Salfi* repeatedly stressed that a suit that does not challenge the constitutionality of the Social Security Act itself but simply asserts that the individual has certain rights under the Act, as respondents contend here, must be brought pursuant to 42 U.S.C. 405(g), after exhaustion of administrative remedies. 422 U.S. at

such a ruling on the ground that it was issued in violation of the Social Security Act is indisputably a claim "arising under" that Act within the meaning of Section 405(h). To paraphrase the language of *Salfi* (422 U.S. at 762, quoted at page 22, *supra*), Section 405(h) bars jurisdiction under 28 U.S.C. 1331 irrespective of whether resort to judicial processes is necessitated by the discretionary decision of an intermediary, an ALJ, or the Appeals Council denying benefits because the medical procedure was found not to be reasonable and necessary on the basis of evidence received in the particular case, or by their nondiscretionary application of an allegedly unlawful ruling of general applicability issued by the Secretary barring payment on the same grounds. See *Association of American Medical Colleges* v. *Califano*, 569 F.2d 101, 107 (D.C. Cir. 1977).

2. The court of appeals attempted to avoid the preclusive effect of 42 U.S.C. 405(h) by characterizing respondents' claim as "procedural" in nature rather than a substantive claim for benefits—*i.e.*, as a challenge to the Secretary's assertedly "unlawful interference" in the administrative adjudication of individual cases (Pet. App. 3a) by adopting a "presumptive rule" that BCBR is not a reasonable and necessary service covered by Medicare (*id.* at 5a). The court reasoned that Section 405(h) is to be given a "relatively narrow scope" (Pet. App. 4a) and should not be read to bar jurisdiction under 28 U.S.C. 1331 to entertain such "procedural" claims (Pet. App. 4a-6a). This reasoning, too, flies in the face of *Salfi*.

The Court observed in *Salfi* that the third sentence of Section 405(h) is "sweeping and direct" and stressed that it is *not* to be construed narrowly. 422 U.S. at 757. See *Attorney Registration and Disciplinary Comm'n* v.

789-790, 791-793 & nn.6 & 8, 795, 797 (Brennan, J., dissenting). The dissenting opinion disagreed with the majority's holding that the third sentence of Section 405(h) also bars constitutional attacks on the statute itself under 28 U.S.C. 1331. 422 U.S. at 789-797.

Schweiker, No. 83-1132 (7th Cir. Aug. 11, 1983), slip op. 5; *Association of American Medical Colleges* v. *Califano*, *supra*, 569 F.2d at 106. Moreover, what the court of appeals in this case characterized as a "procedural" claim outside the scope of the jurisdictional bar in Section 405(h) is essentially identical for present purposes to the claim found in *Salfi* itself to fall squarely within the scope of that bar. The plaintiffs in *Salfi* challenged the duration-of-relationship prerequisite to the receipt of survivors benefits on the similar ground that it created an impermissible "irrebuttable presumption" [14] that a relationship of less than nine months' duration was a sham; the plaintiffs there, like respondents here, contended that they instead should be given an opportunity to have the relevant issue decided on a case-by-case basis in the course of administrative proceedings on their individual claims. See 422 U.S. at 753, 767-768, 770-772, 782-785. The holding in *Salfi* foreclosing jurisdiction under 28 U.S.C. 1331 therefore applies equally here, irrespective of the "procedural" label respondents and the court of appeals attach to the issue.

Although it is not directly relevant to the jurisdictional issues involved in this case, we also note that the Court's recent decision in *Heckler* v. *Campbell* sustaining the Secretary's disability grid regulations demonstrates that the Secretary does *not* impermissibly interfere with the adjudication of individual cases by adopting rules of general applicability to resolve "certain classes of issues" (slip op. 9). The Secretary's promulgation of rules and instructions for this purpose under the Medicare Program is authorized not only by 42 U.S.C. 405(a), relied upon by the Court in *Heckler* v. *Campbell*, *supra*, slip op. 7-8, but also by 42 U.S.C. 1395ff(a), which expressly provides for the Secretary to determine Part A Medicare claims "in accordance with regulations prescribed by [her]."

---

[14] See 422 U.S. at 753 and 770-772, citing *Cleveland Board of Education* v. *LaFleur*, 414 U.S. 632 (1974); *Vlandis* v. *Kline*, 412 U.S. 441 (1973); and *Stanley* v. *Illinois*, 405 U.S. 645 (1972).

Such rules must be sustained unless shown to be arbitrary and capricious. *Heckler* v. *Campbell*, *supra*, slip op. 7-8. The Secretary's determinations with respect to BCBR—based on relevant data and other available scientific material, the expert advice of special advisory groups, and the fact that the procedure is not generally accepted by the medical profession as safe and effective—clearly are not invalid under this standard. They also are well suited to resolution in the context of a rule of general applicability rather than case-by-case adjudication. Compare *Heckler* v. *Campbell*, *supra*, slip op. 9-10.

The merits of the Secretary's BCBR ruling to one side, however, even if respondents' challenge were correctly characterized as "procedural," there is another reason why this characterization would not remove it from the bar in Section 405(h) to federal question jurisdiction. The issue involved in *Mathews* v. *Eldridge*—whether the plaintiffs were entitled to a hearing prior to the termination of their disability benefits—manifestly was "procedural" in nature, and yet the Court made clear that an action presenting that issue under 28 U.S.C. 1331 would be barred by Section 405(h) and instead had to be brought pursuant to 42 U.S.C. 405(g). 424 U.S. at 327. See *Califano* v. *Sanders*, 430 U.S. 99, 109 (1977); cf. *Ellis* v. *Blum*, 643 F.2d 68, 77-78 (2d Cir. 1981). See also *Califano* v. *Yamasaki*, 442 U.S. 682, 697-698 (1979).

3. Respondents also seek to distinguish *Salfi* by asserting (Br. in Opp. 19-21) that the plaintiffs there sought an award of benefits, while in this case respondents seek only a declaratory judgment and injunction preventing the Secretary from enforcing the BCBR rulings, leaving the actual award of benefits to further administrative proceedings. Contrary to respondents' contention, however, the "sweeping and direct" bar in Section 405(h) to jurisdiction under 28 U.S.C. 1331 cannot be so transparently evaded. *Salfi* itself establishes as much. In addition to seeking an award of benefits, the plaintiffs in *Salfi* sought a declaratory judgment that the statutory provisions were unconstitutional and injunctive

relief prohibiting the Secretary from relying on those provisions to deny benefits in administrative proceedings (App. at 12-13, *Weinberger* v. *Salfi*, *supra* (No. 74-214, 1974 Term)); but the Court did not find jurisdiction under 28 U.S.C. 1331 for those aspects of the plaintiffs' suit either.[15]

It necessarily follows from *Salfi* that respondents in this case cannot split off one of the legal arguments in support of their claims for benefits (*i.e.*, that HCFA's intermediary instructions and BCBR ruling are invalid) and present that argument in a separate action under 28 U.S.C. 1331, with the intent of subsequently pursuing their administrative remedies armed with a judicial holding on the validity of the BCBR rulings.[16] The "final decision" after completion of administrative proceedings, if adverse to the claimant, would be subject to judicial review under 42 U.S.C. 405(g), thereby initiating a *second* round of proceedings in court on the same benefits claim. And under respondents' view, this course would be available in *any* case in which a regulation or instruction issued by HHS may have some bearing on a benefit claim.[17] To permit claimants to pursue such a

---

[15] The dissenting opinion in *Salfi* in fact argued that even if an award of benefits in a suit under 28 U.S.C. 1331 is barred by Section 405(h), a suit under 28 U.S.C. 1331 should not be barred if it sought only declaratory and injunctive relief requiring the Secretary to ignore the statutory duration-of-relationship requirement in subsequent administrative proceedings on individual benefit claims. But the dissent nevertheless understood the majority to have held otherwise. See 422 U.S. at 788-789, 797-799 & n.13 (Brennan, J., dissenting).

[16] As noted above (see note 8, *supra*), counsel for respondents requested the Appeals Council to stay administrative proceedings pending a decision by the district court on that issue.

[17] Under respondents' view, for example, the challenge to the grid regulations involved in *Heckler* v. *Campbell* also could have been brought under 28 U.S.C. 1331—rather than pursuant to 42 U.S.C. 405(g) after full exhaustion of administrative remedies, as actually occurred (slip op. 4-5)—if the plaintiff did not seek an actual award of benefits and purported only to challenge the "procedure" by which the Secretary decided an issue in a disability case by refer-

course would substantially disrupt the efficient administration of the various titles of the Social Security Act and would result in the waste and duplication of scarce administrative and judicial resources.

For the foregoing reasons, *all* issues bearing on a claimant's entitlement to payments under the Social Security Act must be channeled through whatever special review procedures Congress and the Secretary have established under that Act. Other courts of appeals have adhered to this view. They have recognized that when a claimant brings an action seeking to clear the way to receipt of benefits under the Social Security Act in the future by urging the court to invalidate an administrative regulation or interpretation of the Act that serves to limit or bar an award in administrative proceedings, the action falls within the scope of the jurisdictional bar in 42 U.S.C. 405(h) and therefore cannot be brought under 28 U.S.C. 1331. See *V.N.A. of Greater Tift County, Inc.* v. *Heckler*, 711 F.2d 1020, 1024-1027 (11th Cir. 1983); *Attorney Registration and Disciplinary Comm'n* v. *Schweiker*, *supra*, slip op. 5-6; *Hadley Memorial Hospital, Inc.* v. *Schweiker*, 689 F.2d 905, 908-910 (10th Cir. 1982); *Hopewell Nursing Home, Inc.* v. *Schweiker*, 666 F.2d 34, 39-40 (4th Cir. 1981)[18]; *Humana of South*

---

ence to general regulations. Such an approach would have forced the Court to review the grid regulations in the abstract, without a full appreciation of the manner in which they would be applied in a particular case.

[18] Although the Fourth Circuit adhered to this view in *Hopewell Nursing Home*, cited in the text, its recent decision in *Starnes* v. *Schweiker*, No. 82-1543 (Aug. 16, 1983), takes a conflicting position. The latter case was brought by Medicare Part B beneficiaries and physicians who furnished services challenging instructions issued to Part B carriers that limited the amount of reimbursement for a particular service. They contended, *inter alia*, that the instructions were not consistent with the statute and were not promulgated in accordance with the rulemaking provisions of the APA. The court of appeals held that, under this Court's decision in *Erika*, the district court did not have jurisdiction over the case insofar as the plaintiffs sought review of decisions by Part B carriers on *past* claims. *Starnes*, *supra*, slip op. 10-11. However, the court held that

Carolina, Inc. v. *Califano*, 590 F.2d 1070, 1079 (D.C. Cir. 1978);[19] *Rhode Island Hospital* v. *Califano*, 585 F.2d

---

neither *Erika* nor 42 U.S.C. 405(h) bars a suit brought under 28 U.S.C. 1331 to prevent carriers and the Secretary from applying the instructions in the future. Slip op. 11-17.

This decision is clearly wrong, for two separate reasons. First, it permits Part B beneficiaries to avoid the holding in *Erika* simply by filing a suit in federal district court prior to receiving a final decision on a reimbursement claim from the carrier, thereby substantially undermining the congressional intent to keep Part B disputes out of the courts. Second, and more generally, it permits a claimant to avoid the explicit jurisdictional bar in 42 U.S.C. 405(h) simply by omitting a request for monetary relief, despite the Fourth Circuit's acknowledgment (*Starnes*, *supra*, slip op. 17) that the plaintiffs there sought judicial invalidation of the instruction in order to pave the way to greater reimbursement in administrative proceedings.

The Fourth Circuit appears to have been influenced in part by the fact that carrier decisions on individual claims are not subject to judicial review under Part B, thereby foreclosing all review of the Secretary's instructions unless the court was able to find jurisdiction under some other provision, such as 28 U.S.C. 1331. See *Starnes*, *supra*, slip op. 14, 16-17. To the extent this was the court's rationale, it has no application here, because the Medicare beneficiary respondents in this case have a right of judicial review under 42 U.S.C. 405(g) if the Secretary ultimately denies their Part A claims. In any event, and contrary to the Fourth Circuit's view, preclusion of judicial supervision of the Secretary's administration of the Part B Medicare Program— involving more than 150 million claims annually—is *precisely* what Congress intended (except, perhaps, in the case of certain constitutional issues, cf. *Schweiker* v. *McClure*, 456 U.S. 188 (1982)). The Fourth Circuit, understandably, was not confident about the result it reached, for it stated that it regarded the question as a "close" one and that a "higher reviewing court" might be of the opinion that it had misconstrued Section 405(h) and the decision in *Erika* (*Starnes*, *supra*, slip op. 18).

[19] In *Humana*, the D.C. Circuit did hold that an objection to the Secretary's failure to follow the notice and comment procedures of the Administrative Procedure Act before promulgating a rule could be brought under 28 U.S.C. 1331, even though a substantive challenge to the validity of the rule could not. 590 F.2d at 1079-1082. This distinction between substantive and procedural challenges to the validity of a single regulation that may have a bearing on a reimbursement issue finds no support in the Act or common sense. As we explain below (see pages 30-32, *infra*), federal question jurisdiction over procedural APA claims also is barred by Section 405(h).

1153, 1158 (1st Cir. 1978); *Dr. John T. MacDonald Foundation, Inc.* v. *Califano*, 571 F.2d 328, 331-332 (5th Cir.) (en banc), cert. denied, 439 U.S. 893 (1978). See also *National Ass'n of Home Health Agencies* v. *Schweiker*, 690 F.2d 932, 938 (D.C. Cir. 1982), cert. denied, No. 82-991 (Feb. 22, 1983); *Association of American Medical Colleges* v. *Califano*, *supra*, 569 F.2d at 106-108.

4.a. There is an additional reason why the statutory scheme cannot be read to embody a congressional intent to permit judicial challenges to regulations and instructions issued by the Secretary to be brought in a separate action under 28 U.S.C. 1331, notwithstanding the explicit jurisdictional bar in 42 U.S.C. 405(h). Not long after Section 405(h) was passed in 1939, Congress enacted the Administrative Procedure Act in 1946 to provide, *inter alia*, for participation by members of the public in the development of rules by federal agencies. Act of June 11, 1946, ch. 324, 60 Stat. 237 *et seq.* Section 4 of that Act (60 Stat. 238), the substance of which is now codified at 5 U.S.C. 553, requires agencies to provide notice of proposed rulemaking and to give interested persons "an opportunity to participate in the rule making through submission of written data, views, or arguments." These requirements ensure the public the right to bring their factual and legal objections to a rule to the attention of the agency in an effort to have the proposal modified or set aside administratively.

Significantly, however, Congress expressly exempted from the notice-and-comment requirements of the APA "any matter relating to * * * benefits" (60 Stat. 238; 5 U.S.C. 553(a)(2)) — a provision that clearly was understood to apply to Social Security programs. See *Attorney General's Manual on the Administrative Procedure Act* 27 (1947); *Humana of South Carolina, Inc.* v. *Califano*, *supra*, 590 F.2d at 1082-1084. This exemption was included because Congress believed that "the principal considerations in most such cases relate to mechanics and interpretations of policy, and it is deemed wise to

encourage and facilitate the issuance of rules by dispensing with all mandatory procedural requirements." S. Rep. No. 752, 79th Cong., 1st Sess. 13 (1945); see also H.R. Rep. No. 1980, 79th Cong., 2d Sess. 23 (1946).

It is inconceivable that, although Congress did not even confer on Social Security beneficiaries a right to present the *Secretary* with their factual and legal objections to a rule, it nevertheless implicitly furnished those beneficiaries with a right to invoke the judicial process in a separate action under 28 U.S.C 1331 to raise those objections, notwithstanding the explicit jurisdictional bar in 42 U.S.C. 405(h). The enactment of the APA therefore strongly reinforces the conclusion that challenges to the validity of rulings and instructions issued under the Social Security Act must first be presented in administrative proceedings in connection with the individual's claim for benefits and may be raised on judicial review only under 42 U.S.C. 405(g) in the event that the Secretary ultimately denies a claim for benefits on the basis of the rulings and instructions. As in *Salfi*, the result is simply to channel all objections to the denial of benefits through the special statutory review procedure Congress has established. The APA reinforces this conclusion in another respect as well, for it provides that the form of proceeding for judicial review of agency action, which includes the issuance of rules, is the special statutory review proceeding relevant to the subject matter (5 U.S.C. 703)—in this case, 42 U.S.C. 405(g) and 1395ff(b), which permit a claimant to challenge a rule in connection with his claim for benefits.

b. In view of the express statutory exemption from APA rulemaking procedures for matters relating to "benefits," it would seem to be especially clear that 42 U.S.C. 405(h) bars jurisdiction under 28 U.S.C. 1331 over a challenge to the Secretary's failure to follow notice-and comment procedures when issuing rules and instructions under the Social Security Act. Yet respondents raised such a claim in district court (J.A. 20-22), and, quite surprisingly, a number of courts actually have held that

jurisdiction over such an "APA" rulemaking claim does lie under 28 U.S.C. 1331.[20] We submit, however, that it is perverse for these courts to conclude that a challenge to a Social Security regulation on the ground that it violates the Social Security Act or even the Constitution (which clearly *do* impose limits on the Secretary's authority) nevertheless must be channeled through 42 U.S.C. 405(g), but that a challenge to a regulation on the ground that it was not issued in conformity with the rulemaking provisions of the APA (which do *not* apply to Social Security benefit programs) may be brought wholly outside this special statutory scheme. See, *e.g.*, *Humana of South Carolina, Inc.* v. *Califano*, *supra*, 590 F.2d at 1082-1084. Other courts have properly rejected this position.[12]

In 1970, the Secretary did issue a memorandum to all components of the Department directing them, as a matter of policy, to follow notice-and-comment procedures when issuing rules in areas that fall within the APA exemption for matters relating to benefits. This memorandum subsequently was published in the *Federal Register*. 36 Fed. Reg. 2532 (1971). See also 47 Fed. Reg. 26860 (1982). The courts seem to have assumed that simply by virtue of publication, this memorandum attained the force of law and created rights enforceable by private parties in court.[22] But in fact it does not appear that the memorandum and accompanying announcement ever were intended to be more than their terms suggest: a statement of internal policy. See *Independent Meat Packers Ass'n*

---

[20] See, *e.g.*, *Starnes* v. *Schweiker*, *supra*, slip op. 15-17; *National Ass'n of Home Health Agencies* v. *Schweiker*, *supra*, 690 F.2d at 936-937; *Humana of South Carolina, Inc.* v. *Califano*, *supra*, 590 F.2d at 1080-1081; *Daniel Freeman Memorial Hospital* v. *Schweiker*, 656 F.2d 473, 476 (9th Cir. 1981).

[21] *Hadley Memorial Hospital, Inc.* v. *Schweiker*, *supra*, 689 F.2d at 910-912; *American Ass'n of Councils of Medical Staffs* v. *Califano*, 575 F.2d 1367, 1370-1373 (5th Cir. 1978).

[22] *Humana of South Carolina, Inc.* v. *Califano*, *supra*, 590 F.2d at 1084 & n.102. See *Rodway* v. *Department of Agriculture*, 514 F.2d 809, 814 (D.C. Cir. 1975).

v. *Butz*, 526 F.2d 228, 235-236 (8th Cir. 1975). Cf. *United States* v. *Caceres*, 440 U.S. 741, 754 n.18 (1979).[23]

However that may be, the publication of the policy statement in 1971 clearly did not make the rulemaking provisions of the APA applicable in their own right to Social Security programs. The statutory exemption Congress enacted remains in effect, and as a result, the APA rulemaking provisions do not furnish an independent basis for a court to invalidate the instructions and HCFA ruling respondents challenge. Compare *United States* v. *Caceres*, *supra*, 440 U.S. at 753-754. The Secretary's authority to direct that notice-and-comment rulemaking be followed in Social Security benefit programs instead derives from her authority under 42 U.S.C. 405(a) and related provisions to promulgate rules and regulations for the administration of the Social Security Act. Any rights conferred on respondents by the 1971 publication of the policy statement regarding notice-and-comment procedures therefore are ones "arising under" the Social Security Act itself, in the same manner as their substantive claims for benefits. It necessarily follows that because of the jurisdictional bar in 42 U.S.C. 405(h), respondents cannot bring an action under 28 U.S.C. 1331 to raise the notice-and-comment issue. They may raise that claim only on judicial review of a denial of benefits under 42 U.S.C. 405(g). This conclusion is eminently reasonable, for it gives the Secretary the opportunity in administrative proceedings to determine the effect of a failure to follow her own policy directive, just as she may interpret and apply substantive regulations in administrative proceedings on a claim for benefits.

5. In addition to finding federal question jurisdiction under 28 U.S.C. 1331, the court of appeals held that the district court had mandamus jurisdiction under 28 U.S.C.

---

[23] In May 1982, the Secretary proposed a regulation to clarify that the Department's policy of following notice-and-comment procedures is internal only and not judicially enforceable. 47 Fed. Reg. 26860-26861.

1361 to entertain respondents' "procedural" claim (Pet. App. 10a). In *Califano* v. *Yamasaki* and *Mathews* v. *Eldridge*, this Court found it unnecessary to determine whether 42 U.S.C. 405(h) entirely bars mandamus jurisdiction under 28 U.S.C. 1361 over any action arising under the Social Security Act, because jurisdiction over the prerecoupment and pretermination hearing issues in those cases was found under 42 U.S.C. 405(g). See 442 U.S. at 698; 424 U.S. at 332 n.12. See also *Norton* v. *Mathews*, 427 U.S. 524, 529-530 (1976). In our view, however, the exercise of mandamus jurisdiction in this case was clearly barred by 42 U.S.C. 405(h). Indeed, in *Salfi* itself, the plaintiffs asserted in district court that jurisdiction over the essentially identical "procedural" objection to an irrebuttable presumption against eligibility rested on 28 U.S.C. 1361 as well as 28 U.S.C. 1331 (App. at 7, *Weinberger* v. *Salfi*, *supra* (No. 74-214, 1974 Term)), and yet the Court held that the action had to be brought under 42 U.S.C. 405(g) because it was one seeking to recover on a claim arising under the Social Security Act.

The third sentence of Section 205(h) of the Social Security Act (42 U.S.C. 405(h)), as originally enacted, provided that an action may not be brought under Section 41 of Title 28 of the United States Code to recover on a claim arising under Title II of the Act. See note 12, *supra*. As the Court explained in *Weinberger* v. *Salfi* (422 U.S. at 756 n.3), at that time Section 41 of Title 28 contained all of that Title's grants of jurisdiction to federal district courts, except for special purpose jurisdictional statutes of no relevance to Social Security cases. The mandamus statute was not then in force and was not enacted until 1962. Pub. L. No. 87-748, Section 1(a), 76 Stat. 744.[24] It nevertheless would be consistent with the

[24] The express reference in the 1976 edition of 42 U.S.C. 405(h) to 28 U.S.C. 1331 and 1346 was substituted for the reference to Section 41 of Title 28 by the codifiers (see 42 U.S.C. 405 note, at 518), whose "choice, 'made * * * without the approval of Congress * * * should be given no weight.'" *North Dakota* v. *United States*, No. 81-773 (Mar. 7, 1983), slip op. 10 n.13, quoting *United States* v. *Welden*, 377 U.S. 95, 99 n.4 (1964).

"sweeping" language of the third sentence of Section 405(h) (see *Weinberger* v. *Salfi*, *supra*, 422 U.S. at 757) to interpret it as barring jurisdiction under the mandamus statute whenever jurisdiction over the particular suit under 28 U.S.C. 1331 also would be barred. A contrary holding would permit circumvention of the clear congressional purpose expressed in 42 U.S.C. 405(g) and (h) to bar judicial review of decisions of the Secretary in administering the Social Security Act except as provided in that Act itself, and thereby to channel all judicial review through 42 U.S.C. 405(g).

In addition, even if the third sentence of Section 405(h) does not foreclose mandamus jurisdiction in all Social Security cases, the exercise of that jurisdiction would in any event be barred in this case by the second sentence of Section 405(h). The second sentence provides that "[n]o findings of fact or decision of the Secretary shall be reviewed by any person, tribunal, or governmental agency except as herein provided." Respondents challenge on the merits the non-final decisions of the Secretary denying their claims for payment for BCBR surgery. Under the second sentence of Section 405(h), it is clear that the Secretary's decision on the merits of a claim for benefits cannot be reviewed by any "tribunal" (including a district court) except as "herein provided"—*i.e.*, pursuant to 42 U.S.C. 1395ff(b) and 405(g), after full exhaustion of administrative remedies. This principle is fully applicable where, as here, the Secretary's decision denying coverage is based on a regulation barring payment. Even the Second Circuit, which has held that mandamus jurisdiction is not entirely foreclosed by Section 405(h), has stated that such jurisdiction is available only to consider "otherwise unreviewable procedural issues not related to merits of a claim for benefits." *Dietsch* v. *Schweiker*, 700 F.2d 865, 868 (2d Cir. 1983). See also *Ellis* v. *Blum*, 643 F.2d 68, 82 (2d Cir. 1981); *White* v. *Mathews*, 559 F.2d 852, 856 (2d Cir. 1977), cert. denied, 435 U.S. 908 (1978). In this case, not only are the procedural issues respondents seek to raise directly related to the merits of their claims for benefits;

they also are reviewable in an action under 42 U.S.C. 405(g).

In any event, well established limitations on the exercise of mandamus jurisdiction make clear that such relief is not available here. Mandamus would lie only if there were no other adequate remedy available and the Secretary owed the plaintiffs a clear duty. *United States ex rel. Girard Trust Co.* v. *Helvering*, 301 U.S. 540, 543-544 (1937). See *Leschniok* v. *Heckler*, No. 82-5676 (9th Cir. Aug. 18, 1983), slip op. 4;[25] *Hadley Memorial Hospital, Inc.* v. *Schweiker*, *supra*, 689 F.2d at 912; *American Healthcare Corp.* v. *Schweiker*, 688 F.2d 1072, 1084 (7th Cir. 1982); *Herzog* v. *Secretary of HEW*, 686 F.2d 1154, 1161 n.5 (6th Cir. 1982); *Cervoni* v. *Secretary of HEW*, 581 F.2d 1010, 1020 (1st Cir. 1978); *Association of American Medical Colleges* v. *Califano*, *supra*, 569 F.2d at 110 n.80. See generally 1 J. Moore, *Moore's Federal Practice* ¶ 0.62[17] (2d ed. 1982). Neither requirement is satisfied in this case.

As we have explained, respondents have a fully adequate remedy under 42 U.S.C. 1395ff(b) and 405(g) to challenge the Secretary's decision denying payment for BCBR, including any objections to the 1979 intermediary instructions and 1980 ruling if either should ultimately play a role in the Secretary's final decision. Claimants under the Social Security Act cannot avoid the requirement of exhaustion of remedies under these sections simply by bringing a challenge to a regulation under the

[25] The court in *Leschniok* appeared to hold, however, that mandamus jurisdiction *would* be available, without regard to the usual exhaustion requirements, in any case raising a constitutional issue that does not directly seek the payment of benefits; and the court then held that an allegation that the Secretary failed to follow the statute amounts to an allegation of a constitutional violation, because such conduct contravenes the President's duty to take care "that the Laws be faithfully executed" (U.S. Const. Art. II, § 3). Slip op. 9. The effect of this decision converting statutory issues into constitutional ones, if followed, would be to make mandamus jurisdiction immediately available in any case in which the claimant alleges that the Secretary misapplied the statute. We must assume that the Ninth Circuit did not intend to fashion such a massive loophole in the Social Security jurisdictional scheme.

mandamus statute. Moreover, the determination whether BCBR is a reasonable and necessary medical service involves questions of judgment and discretion and the weighing of available data and other evidence. In these circumstances, it scarcely can be said that the Secretary has a clear duty to make payment for BCBR or to rescind the ruling or instructions through which the Secretary has expressed her findings on the question of coverage. Indeed, the Second Circuit recently has expressed the view that mandamus will never lie to challenge the propriety of a regulation, as distinguished from the Secretary's conduct under it. *Smith* v. *Schweiker*, 709 F.2d 777, 779 (1983). These factors strongly reinforce the conclusion that a claimant cannot be permitted to circumvent the congressional policies embodied in 42 U.S.C. 405(g) and (h) and confirmed by this Court in *Salfi* by invoking the mandamus statute.

B. The District Court Did Not Have Jurisdiction Over This Case Under 42 U.S.C. 405(g) Because Respondents Did Not Exhaust Their Administrative Remedies And Obtain A "Final Decision" By The Secretary On Their Individual Benefit Claims

Despite the "procedural" label the court of appeals attached to their claim, it is clear that respondents simply have a substantive disagreement with the denial by the Secretary of claims for payments under Part A of the Medicare Program. Thus, at bottom, this case involves nothing more than a routine Medicare reimbursement dispute. Even the court of appeals acknowledged (Pet. App. 6a-7a) that judicial review of a decision by the Secretary (or by an intermediary acting on her behalf) denying a claim for benefits may be obtained only pursuant to 42 U.S.C. 405(g) after exhaustion of administrative remedies. Yet the court of appeals held that the district court had jurisdiction over respondents' claims under 42 U.S.C. 405(g) even though they had *not* exhausted their administrative remedies (Pet. App. 6a-10a). This holding, like the court's finding of jurisdiction under 28 U.S.C. 1331 notwithstanding the explicit jurisdictional bar in 42 U.S.C. 405(h),

is directly contrary to the statutory text and this Court's decisions.

1. The exhaustion requirement derives from the language in 42 U.S.C. 405(g) providing that judicial review is available under that Section only where there has been a "final decision" by the Secretary "after a hearing" on the claim for benefits. This explicit requirement is reiterated in the judicial review section of the Medicare Act, 42 U.S.C. 1395ff(b)(1)(C). See also 42 U.S.C. (Supp. V) 1395*oo*(f)(1).

Only three of the five respondents in this case—Holmes, Webster-Zieber and Vescio—ever even filed a claim for benefits under Medicare for BCBR surgery. This Court repeatedly has made clear that the filing of an application for benefits is an absolute jurisdictional prerequisite to bringing an action under 42 U.S.C. 405(g), because without such an application, there can be no "decision" whatever by the Secretary on the claim. See *Weinberger* v. *Salfi*, *supra*, 422 U.S. at 764; *Mathews* v. *Eldridge*, *supra*, 424 U.S. at 328-329; *Mathews* v. *Diaz*, 426 U.S. 67, 75 (1976); *Califano* v. *Yamasaki*, *supra*, 442 U.S. at 704; *Heckler* v. *Lopez*, No. A-145 (Sept. 9, 1983), slip op. 7 (Rehnquist, Circuit Justice); cf. *Schweiker* v. *Hansen*, 450 U.S. 785, 790 (1981). For this reason, as the court of appeals held (Pet. App. 9a n.4), the district court clearly had no jurisdiction under 42 U.S.C. 405(g) with respect to any matters pressed on behalf of respondent Ringer or other individuals who had not filed such an application.[26] Nor does respondent Win-

[26] As typically is the case in insurance programs generally, a claim may be filed under Medicare (thereby invoking the administrative process that must precede the right to judicial review under 42 U.S.C. 405(g)) only *after* the individual has been furnished the services for which payment is sought. See 42 U.S.C. (& Supp. V) 1395c, 1395d(a), 1395f(a), 1395ff(b) and 405(b); 42 C.F.R. 405.1662-405.1667. Congress obviously appreciated that the task of administering the Medicare Program would be burdensome enough with the processing of concrete claims for services already rendered, without also providing for a scheme by which an individual could obtain a declaratory ruling on whether certain services would be covered should the individual elect to obtain them in the future.

ter, the physician who performs the BCBR surgery, have any standing in his own right to bring an action under 42 U.S.C. 405(g) on the question of Medicare coverage for BCBR. See *Attorney Registration and Disciplinary Comm'n* v. *Schweiker*, *supra*, slip op. 7.

Although respondents Holmes, Webster-Zieber, and Vescio did submit applications for benefits under Part A before the amended complaint in this case was filed, none had pursued his administrative remedies beyond the reconsideration stage. A decision on reconsideration is not the Secretary's "final decision" for purposes of judicial review. As we have explained above, the question of what constitutes the requisite "final decision" for purposes of judicial review is "left to the Secretary to flesh out by regulation" (*Weinberger* v. *Salfi*, *supra*, 422 U.S. at 766), and the governing regulations explicitly provide that such a decision will have been rendered only after the claimant has completed all four steps of the administrative process, including ALJ and Appeals Council review. 42 C.F.R. 405.701(c), incorporating 20 C.F.R. 404.900(a)(5). Because respondents Holmes, Webster-Zieber, and Vescio had not completed the last two steps of the process when the amended complaint was filed (and even now have not received an Appeals Council decision), they failed to satisfy the "statutorily specified jurisdictional prerequisite" to bringing an action under 42 U.S.C. 405(g). *Weinberger* v. *Salfi*, *supra*, 422 U.S. at 766.

2. The court of appeals excused respondents from satisfying the exhaustion requirement because it believed that "[b]y issuing a ruling that purports to bind ALJs and the Appeals Council to the denial of benefits for BCBR operations, the Secretary has indicated that [she] has no interest in appeals at or beyond the ALJ level" (Pet. App. 8a). The court of appeals was simply wrong. It confused a *substantive* rule pertaining to the merits of a claim with a *procedural* rule governing the manner in which a claim must be presented to the Secretary for decision. The 1980 HCFA ruling was the

former, and had no bearing on the exhaustion issue. Cf. *Heckler* v. *Lopez*, *supra*, slip op. 8 (Rehnquist, Circuit Justice) ("there is no decision of this Court that has interpreted the Secretary's announcement of her interpretation of a Social Security statute as a waiver of the exhaustion requirement"). When the Secretary has intended to permit a claimant to bypass the administrative process, she has explicitly so provided in her procedural rules. But she has not done so for respondents' claims.

The Court stressed in *Salfi* that "the Secretary may specify such requirements for exhaustion as [she] deems serve [her] own interests in effective and efficient administration" and that the statutory scheme therefore does not bar the *Secretary* from determining in certain circumstances that full internal exhaustion is not necessary in order for her to deem a decision denying benefits to be administratively "final" for purposes of judicial review. 422 U.S. at 766-767. In *Salfi* itself, the plaintiffs represented that the Secretary had correctly found the relevant facts regarding the duration of their relationship to the decreased wage earner; that they did not dispute his interpretation or application of the relevant statutory provisions to deny their claims; and that the only issue remaining was the constitutionality of those statutory provisions, a matter that was beyond the competence of the Secretary to decide. 422 U.S. at 765; App. at 11, *Weinberger* v. *Salfi*, *supra* (No. 74-214, 1974 Term). The Court held that the Secretary properly could determine in these circumstances that it was unnecessary to require the plaintiffs fully to exhaust their administrative remedies through the Appeals Council stage, because he had "determin[ed] in favor of the applicant, without a hearing, all issues with regard to eligibility save for one [the constitutional issue] as to which he considers a hearing to be useless." 422 U.S. at 767.

Following the decision in *Salfi*, the Secretary promulgated regulations establishing a procedure for expediting the right to judicial review in the circumstances identified in *Salfi*. This expedited procedure is available if the individual's claim has been denied at the reconsider-

ation level, if he does not dispute the Secretary's findings of fact or interpretation or application of controlling law, and if the claimant alleges (and the Secretary agrees) that the only factor precluding a favorable determination is a statutory provision that the claimant contends is unconstitutional. In such a situation, the claimant and a representative of the Secretary may enter into a formal agreement stipulating to the existence of these conditions and deeming the decision on reconsideration "final" for purposes of judicial review without requiring the claimant to request an ALJ hearing or Appeals Council review. 42 C.F.R. 405.718-405.718c.[27] The individual then has 60 days within which to seek judicial review. 42 C.F.R. 405.718d.

In promulgating these regulations, the Secretary explained that where the specified conditions have been satisfied, he could be confident that the claim had been presented at a sufficiently high level to afford an opportunity to correct errors; to have a complete record with respect to the facts, law, and possible alternative bases of entitlement; and to insure national uniformity. 40 Fed. Reg. 53385 (1975). In these circumstances, the Secretary determined, further pursuit of administrative proceedings would be "clearly futile." *Ibid.* However, in accordance with the Court's admonition in *Salfi* that "a court may not substitute its conclusion as to futility for the contrary conclusion of the Secretary" (422 U.S. at 767), the Secretary explained that the denial of a claimant's request to pursue the expedited procedure[28] "will not be subject to the right to administrative or judicial review." 40 Fed. Reg. 53385.

The procedures adopted by the Secretary in cases raising constitutional issues assure that the question of exhaustion of administrative remedies itself will be

---

[27] If the individual already has requested an ALJ hearing or Appeals Council review, the agreement to invoke the expedited judicial review procedure must be approved by the chief ALJ or the Appeals Council, respectively. 42 C.F.R. 405.718c(a)(2).

[28] See 42 C.F.R. 405.718e (request will be denied when the Secretary concludes that not all conditions have been satisfied).

presented to and be expressly ruled upon by the Secretary in each case and that judicial review will be accelerated only on the basis of a specific finding by the Secretary that the particular claim in issue need not be reviewed further administratively. Moreover, as the government explained to this Court in its Supplemental Brief in *Mathews* v. *Diaz*, when the regulations implementing *Salfi* were being considered for promulgation in September 1975 (Supp. Br. for Appellant at 5 n.2, *Mathews* v. *Diaz*, *supra* (No. 73-1046, 1975 Term)), the regulations assure consistent treatment of a broad range of cases that claimants may assert are ripe for immediate judicial review. The formal procedure for dispensing with the exhaustion requirement also guarantees that the claimant and the Secretary have formally stipulated to the fact that further exhaustion may be dispensed with in the particular case, thereby making it unnecessary for the parties to engage in extensive litigation on this question in subsequent judicial proceedings and unnecessary for the court in those proceedings to infer from what otherwise might be ambiguous circumstances whether the Secretary had actually concluded that further administrative proceedings are not required.

In contrast to the special category of cases raising constitutional issues, the Secretary has not authorized avoidance of full exhaustion of administrative remedies in any other circumstances—including those, as here, in which the claimant challenges a ruling or instruction issued by the Secretary. Her express provision for such a procedure in the one limited category but not in others establishes that the Secretary deliberately foreclosed any such bypass in other cases. *Lehman* v. *Nakshian*, 453 U.S. 156, 162-163 (1981). The court of appeals failed to respect this judgment.

Indeed, given the detailed restrictions in the special regulations relating to constitutional questions, it is untenable to suppose that the Secretary would dispense with exhaustion of administrative remedies in the wholesale and cavalier manner the court of appeals has permitted in this case. The court of appeals' opinion does not require that the issue of exhaustion itself be pre-

sented to the Secretary for decision in each individual claimant's case, as is required by the regulations permitting accelerated judicial review of claims raising a constitutional attack on the Social Security Act. The court of appeals instead has allowed an abrogation of exhaustion principles for any claimant allegedly affected by a regulation. Moreover, respondents clearly *do* challenge the Secretary's interpretation and application of the statutory provision barring payment for services that are not reasonable and necessary, and there has been no stipulation by respondents and the Secretary that they are in agreement on the proper resolution of any factual issues involved. Either of these factors alone would disqualify respondents from resort to the special expediting procedure the Secretary has established in the case of constitutional issues. Finally, unlike the constitutional issue presented in *Salfi*, the question respondents seek to raise —the coverage of BCBR under Medicare—not only is within the competence of the Secretary, but is one that Congress has expressly directed her to decide. 42 U.S.C. 1395ff(a). Thus, none of the factors supporting the exception to the exhaustion requirement recognized in the Secretary's regulations implementing *Salfi* supports the court of appeals' circumvention of the regulations requiring ALJ and Appeals Council review before an action may be brought under 42 U.S.C. 405(g).[29] But even if the court of appeals believed otherwise, the court was not authorized to excuse respondents from satisfying the requirement of ALJ and Appeals Council review. That is a matter for the Secretary to decide.[30]

---

[29] Respondents rely (Br. in Opp. 8, 10, 12, 16) on *Mathews* v. *Diaz* to excuse exhaustion here. But in *Diaz*, as in *Salfi*, there was agreement between the parties that no facts were in dispute in the individual case and that the only issue to be resolved was the constitutionality of a statutory provision that was beyond the Secretary's competence to decide. 426 U.S. at 76-77 n.11. Moreover, the proceedings in district court in *Mathews* v. *Diaz* occurred before the Secretary adopted regulations to bring order to the determination of when a "final decision" has been rendered.

[30] Other courts of appeals have recognized that administrative remedies must be exhausted before seeking judicial review even

3. Although a claimant who does not qualify under the regulations applicable to cases raising only constitutional issues cannot wholly bypass the ALJ and Appeals Council stages, as respondents attempted to do in this case, applicable regulations do provide a separate mechanism by which that process may be expedited. If the claimant believes that an oral hearing is unnecessary in his case, he may request that the ALJ decide it on the written record without an oral hearing. 42 C.F.R. 405.701(c), incorporating 20 C.F.R. 404.948 (b). The Secretary's operating instructions provide that such cases are to be given "immediate attention" by the ALJ. If the ALJ agrees with the claimant, after a review of the claims file, that an oral hearing is not necessary, the ALJ is expected to issue his decision within 30 days of his receipt of the claims file. Social Security Administration, U.S. Dep't of Health and Human Services, *Office of Hearings and Appeals Handbook*, Pt. 1, § 1-313(4) (Apr. 1982); see also *id.* at Pt. 2, § 2-1331. Under these provisions, if a claimant believes that the relevant facts are not in dispute and that his case will be governed at the ALJ stage by a regulatory provision that binds the ALJ, the case would appear to be suitable for disposi-

---

where the court believes that the particular issue on which judicial review is sought is unlikely to be resolved in the claimant's favor at the administrative level. See, *e.g.*, *Hopewell Nursing Home, Inc.* v. *Schweiker*, *supra*, 666 F.2d at 40, 42; *Humana of South Carolina, Inc.* v. *Califano*, *supra*, 590 F.2d at 1075-1076; *Rhode Island Hospital* v. *Califano*, *supra*, 585 F.2d at 1159; cf. *Hadley Memorial Hospital, Inc.* v. *Schweiker*, *supra*, 689 F.2d at 912.

This is Congress' understanding of the statutory scheme as well. In 1980, Congress amended 42 U.S.C. 1395oo(f), which provides for judicial review of reimbursement decisions under Part A by the Provider Reimbursement Review Board in a manner similar to that provided for individual claims under 42 U.S.C. 405(g), to authorize immediate judicial review of a question of law or regulations whenever *the Board* determines that it is without authority to decide the question. This indicates that the solution preferred by Congress when a case presents a legal question that cannot be resolved at the administrative level likewise is not to permit a court to excuse exhaustion, as the court of appeals did here, but to provide a mechanism for the Secretary to expedite that exhaustion. See

tion under this expedited procedure.[31] Similarly, if the Appeals Council is satisfied on a request for review that no other matters are in issue and the claim is controlled by a formal ruling or regulation that binds the Appeals Council, it ordinarily could be expected to deny the request for review promptly and thereby clear the way for judicial review.

Against this background, there is no reason to believe that the requirement of exhaustion of administrative remedies through the Appeals Council stage will cause substantial hardship or delay for those claimants whose cases actually are governed by a regulation that bars recovery at the administrative level and who genuinely desire to expedite the administrative process. Respondents, however, made no such effort.[32]

On the other hand, the requirement that claimants exhaust their administrative remedies before presenting their claims to a court, despite a rule that appears to bar an award in administrative proceedings, does further important governmental interests under the Social Security Act. It furnishes the ALJ and the Appeals Coun-

---

National Ass'n of Home Health Agencies v. *Schweiker*, *supra*, 690 F.2d at 939. Moreover, the legislative history shows that Congress recognized that "[u]nder present law," judicial review is not available on an isolated legal issue until the Board has rendered a final decision on the entire case. H.R. Rep. No. 96-1167, 96th Cong., 2d Sess. 394 (1980).

[31] We note in this regard that, according to data compiled by the Appeals Council in its July 22, 1983 letter to counsel for respondents (see note 8, *supra*), some 16 BCBR cases pending before the Appeals Council on requests for review were decided by ALJs without an oral hearing because it was thought that such hearings were unnecessary in view of the HCFA ruling that bound the ALJ. In *In re Winter*, the consolidated ALJ decision involving 132 BCBR claimants, the ALJ likewise disposed of 59 cases on the basis of the HCFA ruling (slip op. 1-4, 34-35).

[32] To the contrary, respondents Holmes and Webster-Zieber waited so long to request an ALJ hearing that their request was untimely. We also have been informed by HHS that neither they nor respondent Vescio sought to waive their right to an oral hearing, and they actually requested the Appeals Council to *stay* its consideration of their cases (see note 8, *supra*).

cil with an opportunity to screen pending cases to determine whether the rule in fact applies to particular cases and whether the claims should be granted or denied for reasons unrelated to the rule. If it appears to the ALJ on closer examination that the rule does not apply, he then may receive and review any necessary evidence in order to dispose of the case expeditiously in light of the changed circumstances. That is precisely what happened here. The 1980 HCFA ruling respondents attack was not applied to them because they had BCBR surgery before its effective date, and the ALJ received extensive evidence relating to the coverage of such pre-1980 surgery. Even in the case of post-1980 BCBR surgery, the ALJ might conclude that payment may be made under Medicare because the case falls within one of the exceptions in the 1980 ruling, such as that for situations in which there is a mass in the carotid body (see note 5, *supra*).

The requirement of exhaustion also enables the ALJ to determine whether a particular claim is "invalid for other reasons" (*Weinberger* v. *Salfi*, *supra*, 422 U.S. at 762), quite aside from a challenged rule. The ALJ might conclude, for example, that the individual was not covered by Medicare or that the particular procedure was not "reasonable and necessary" for other reasons. Thus, in the case of BCBR, an ALJ might determine that a particular claimant in fact did not suffer from symptoms that would warrant BCBR surgery even in the circumstances respondent urge. In the instant case, the ALJ found respondents Holmes and Webster-Zieber ineligible for still other reasons: they had failed to request review in the time allowed. See page 13, *supra*.

Similarly, review by the Appeals Council, which has nationwide jurisdiction, serves important purposes that are not significantly addressed at other stages in the administrative process. Appeals Council review helps to ensure that the complex statutory and regulatory provisions governing Social Security claims are uniformly applied by the more than 800 ALJs and thereby to furnish an opportunity to correct erroneous interpretations by individual ALJs. Appeals Council review also may serve to focus

attention on particular issues affecting a number of claimants and provide a catalyst to reassess Departmental policies, as occurred after the decision in *In re Ferguson* regarding BCBR. See pages 8-9, *supra*.

In sum, as the Court observed in *Salfi*, exhaustion prevents "premature interference with agency processes, so that the agency may function efficiently and so that it may have an opportunity to correct its own errors, to afford the parties and the courts the benefits of its experience and expertise, and to compile a record which is adequate for judicial review." 422 U.S. at 765. Only then is judicial review available under 42 U.S.C. 405(g). The court of appeals failed to respect these considerations.

4. The court of appeals also held that this Court's decision in *Mathews* v. *Eldridge* warranted dispensing with the exhaustion requirement here (Pet. App. 9a-10a). This holding, too, was quite mistaken. In *Mathews* v. *Eldridge*, the Court stated that even when the Secretary has determined that the decision on a given claim is not yet final for purposes of seeking judicial review, "cases may arise where a claimant's interest in having a particular issue resolved promptly is so great that deference to the agency's judgment is inappropriate" (424 U.S. at 330). The contention of the plaintiff in *Mathews* v. *Eldridge* that he had a constitutional right to a hearing prior to the termination of his disability benefits was found to be such an issue. The Court relied on two factors. First, the constitutional issue was "entirely collateral to the substantive claim of entitlement." 424 U.S. at 330. Second, the very nature of the plaintiff's asserted constitutional right to a predeprivation hearing rested on the proposition that full relief could not be obtained following a postdeprivation hearing; in view of the plaintiff's physical condition and dependency on disability benefits, the Court concluded that he had made a "colorable claim" that an erroneous prehearing termination of benefits would injure him in a way that would not be recompensable through retroactive payments if he were found eligible after a hearing. *Id.* at 331. Thus, the Court reasoned, unlike in *Salfi*, the

plaintiffs' constitutional challenge would not be answered if his substantive claim were denied "for other reasons" or upheld "under other provisions" in the course of administrative exhaustion. 424 U.S. at 331-333, quoting *Weinberger* v. *Salfi*, *supra*, 422 U.S. at 762.

The factors supporting the exception to the exhaustion requirement recognized in *Mathews* v. *Eldridge* are wholly absent here. Respondents' challenge to the instructions and HCFA ruling barring reimbursement for BCBR is not at all "collateral" to their substantive claim of entitlement; it is intimately bound up with respondents' substantive contention that the BCBR surgery is reasonable and necessary within the meaning of the Medicare Act. Furthermore, in *Mathews* v. *Eldridge*, the court permitted a limited detour from the administrative process only to permit judicial resolution of the collateral issue regarding a pretermination hearing, not the claim to disability benefits on the merits. Here, in contrast, respondents seek to avoid the administrative process entirely by having the court resolve their claims on the merits.

Respondents also have advanced no colorable claim that an erroneous denial of benefits for the BCBR procedure at an early stage in the administrative proceedings will injure them in a way that cannot adequately be remedied if they are subsequently awarded benefits upon a finding by an ALJ, the Appeals Council, or a court that BCBR is a reasonable and necessary procedure. Unlike the plaintiff in *Mathews* v. *Eldridge*, respondents are not receiving benefits that HHS has sought to terminate and on which they might have become dependent.[23] They are simply seeking a one-time reimbursement for a particular medical procedure that has already occurred. And as in *Salfi*, but unlike in *Mathews* v. *Eldridge*, respondents' asserted claim to payment for BCBR will be sufficiently answered if they are awarded benefits notwithstanding the rulings

---

[23] The Court in *Mathews* v. *Eldridge* found even these considerations in a disability case insufficient to require a hearing before benefits are terminated. 424 U.S. at 335-349.

they challenge in this suit or if their benefits are denied for other reasons.

5. Respondents also contend (Br. in Opp. 2, 12, 13-14 n.8, 18-19, 20, 23) that exhaustion of administrative remedies should be excused because they should not be required to "relitigate" in administrative proceedings the question of the coverage of BCBR under Medicare. Respondents argue that the coverage question was decided in favor of the claimants in the Appeals Council's decision in *In re Ferguson* and that, as a result, HCFA was collaterally estopped from issuing the 1980 ruling barring payment for BCBR. This contention is frivolous. To begin with, because the 1980 ruling did not apply to the only three respondents who filed an application for payment for BCBR, they have no standing to challenge it. See page 13, *supra*.

Moreover, the Appeals Council explicitly stated in *In re Ferguson* that its decision was not to be regarded as definitive on the BCBR issue and was not to be cited as precedent in future cases (slip op. 23). The Secretary plainly would not be required to give collateral estoppel to such a decision. But even if the Appeals Council had been more definitive in its prior decision, this could not forever bar the Secretary from taking a different view of the matter. One of the reasons for relying upon rulings of general applicability in administering the Social Security Act is to correct perceived errors and inconsistencies in prior decisions. *Heckler* v. *Campbell*, *supra*. In the case of BCBR, for example, the separate decisions in *In re Ferguson* and *In re Winter* reached opposite conclusions on whether BCBR is a reasonable and necessary procedure.

For these reasons, the weight that should be given in administrative proceedings to a prior administrative ruling in a similar case is itself a question of the procedure to be followed in determining individual claims that Congress has authorized the Secretary to resolve. See 42 U.S.C. 405(a) and 1395ff(a). Cf. *W.R. Grace & Co.* v. *Local 759, Int'l Union of Rubber Workers*, No. 81-1314

(May 31, 1983), slip op. 7-8. And she has done so. Applicable regulations provide that if an issue in an ALJ hearing was decided in a prior case "involving the same parties," the resolution of that issue will not be considered again "unless there are reasons to believe it was wrong." 42 C.F.R. 405.701(c), incorporating 20 C.F.R. 404.950(f). That regulation clearly does not require the application of collateral estoppel in respondents' cases on the basis of decisions involving *other* parties, especially where both the ALJ in *In re Winter* and HCFA in issuing the 1980 ruling found reason to believe that the conclusion reached in the prior decision in *In re Ferguson*, upon which respondents rely, was wrong.

In any event, there is no reason why respondents should not be required to present their collateral estoppel argument in the course of administrative proceedings before presenting it to the courts, just as they must do with respect to other arguments in support of their benefit claims. See *Continental Can Co.* v. *Marshall*, 603 F.2d 590 (7th Cir. 1979). This would permit the ALJ and Appeals Council to conduct an inquiry into the precedential nature of the prior administrative decisions that respondents contend should be given preclusive effect. As we have explained above, the ALJ in *In re Winter*—respondents' case—did exactly that: the ALJ considered the preclusion argument and rejected it, because of the non-precedential nature of the decision in *In re Ferguson*. Moreover, an ALJ or the Appeals Council might conclude that prior decisions should be followed as a matter of administrative stare decisis, thereby obviating any need to resolve the collateral estoppel issue. And exhaustion of administrative remedies on the collateral estoppel issue at least would assure that the court, on judicial review under 42 U.S.C. 405(g), would have the benefit of the Secretary's interpretation of the Social Security Act and implementing regulations with regard to the application of collateral estoppel in the particular administrative proceeding. *Cf. W.R. Grace & Co.* v. *Local 759, Int'l Union of Rubber Workers, supra*, slip op. 7-8.

6. Because respondents can point to no substantial need for immediate judicial review, their argument against exhaustion of administrative remedies reduces to nothing more than a desire to avoid the administrative process for its own sake. This Court has made clear, however, that the mere fact that a party must assume whatever burden might be entailed in participation in administrative proceedings does not constitute irreparable injury warranting the bypassing of those proceedings in favor of immediate judicial review. See, *e.g.*, *FTC* v. *Standard Oil of California*, 449 U.S. 232, 244 (1980). Nor, contrary to respondents' suggestion (Br. in Opp. 21), does the fact that respondents might actually prevail in administrative proceedings and thereby moot the issues on which they now seek judicial review warrant avoiding the administrative proceedings. To the contrary, one of the principal reasons to await a final agency decision is that the agency's consideration of the matter might obviate all occasion for judicial review. 449 U.S. at 244 n.11.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

REX E. LEE
Solicitor General

J. PAUL MCGRATH
Assistant Attorney General

KENNETH S. GELLER
Deputy Solicitor General

EDWIN S. KNEEDLER
Assistant to the Solicitor General

ANTHONY J. STEINMEYER
MARGARET E. CLARK
Attorneys

SEPTEMBER 1983

APPENDIX

STATUTORY PROVISIONS INVOLVED

1. 28 U.S.C. (Supp. V) 1331 provides:

> Federal question
>
> The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States.

2. 28 U.S.C. 1361 provides:

> Action to compel an officer of the United States to perform his duty
>
> The district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff.

3. Sections 205(g) and (h) of the Social Security Act, as codified at 42 U.S.C. (& Supp. V) 405(g) and (h) provide:

> Evidence, procedure, and certification for payments
>
> * * * * *
>
> (g) Judicial review
>
> Any individual, after any final decision of the Secretary made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Secretary may allow. Such action shall be brought in the district court of the United States for the judicial district in which the plaintiff resides, or has his principal place of business, or, if he does not reside or have his principal place of busi-

ness within any such judicial district, in the United States District Court for the District of Columbia. As part of his answer the Secretary shall file a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based. The court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Secretary, with or without remanding the cause for a rehearing. The findings of the Secretary as to any fact, if supported by substantial evidence, shall be conclusive, and where a claim has been denied by the Secretary or a decision is rendered under subsection (b) of this section which is adverse to an individual who was a party to the hearing before the Secretary, because of failure of the claimant or such individual to submit proof in conformity with any regulation prescribed under subsection (a) of this section, the court shall review only the question of conformity with such regulations and the validity of such regulations. The court may, on motion of the Secretary made for good cause shown before he files his answer, remand the case to the Secretary for further action by the Secretary, and it may at any time order additional evidence to be taken before the Secretary, but only upon a showing that there is new evidence which is material and that there is good cause for the failure to incorporate such evidence into the record in a prior proceeding; and the Secretary shall, after the case is remanded, and after hearing such additional evidence if so ordered, modify or affirm his findings of fact or its decision, or both, and shall file with the court any such additional and modified findings of fact and decision, and a transcript of the additional record and testimony upon which his action in modifying or affirming was based. Such additional or modified findings of fact and decision shall be reviewable only to

the extent provided for review of the original findings of fact and decision. The judgment of the court shall be final except that it shall be subject to review in the same manner as a judgment in other civil actions. Any action instituted in accordance with this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(h) Finality of Secretary's decision

The findings and decisions of the Secretary after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Secretary shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Secretary, or any officer or employee thereof shall be brought under sections 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.

4. Sections 1869(a) and (b) of the Social Security Act, as codified at 42 U.S.C. 1395ff(a) and (b), provide:

Determinations of Secretary

(a) Entitlement to and amount of benefits

The determination of whether an individual is entitled to benefits under part A or part B, and the determination of the amount of benefits under part A, shall be made by the Secretary in accordance with regulations prescribed by him.

(b) Appeal by individuals

(1) Any individual dissatisfied with any determination under subsection (a) of this section as to—

(A) whether he meets the conditions of section 426 or section 426a of this title, or

(B) whether he is eligible to enroll and has enrolled pursuant to the provisions of part B of

this subchapter, or section 1395i-2 of this title, or section 1819, or

(C) the amount of benefits under part A (including a determination where such amount is determined to be zero)

shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section 405 (b) of this title and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title.

(2) Notwithstanding the provisions of subparagraph (C) of paragraph (1) of this subsection, a hearing shall not be available to an individual by reason of such subparagraph (C) if the amount in controversy is less than $100; nor shall judicial review be available to an individual by reason of such subparagraph (C) if the amount in controversy is less than $1,000.

☆ U. S. GOVERNMENT PRINTING OFFICE: 1969 416523 81